LEARNING FROM THE PAST: A RETROSPECTIVE ANALYSIS OF INFORMED CONSENT BEFORE THE REVISED COMMON RULE[†‡]

Christopher R. Trudeau[*]

Abstract. Past research and experiences show that many research participants do not know what they are agreeing to because of overly complex, legalistic consent forms that have become overburdened with competing purposes. In January 2019, the Revised Common Rule took effect requiring that information in research consent forms be presented in a way that promotes a research participant's understanding of the study that they are being asked to join. To further promote this purpose, the Revised Common Rule also requires that consent forms begin with key information that is most likely to help people decide why they might or might not want to participate in the research. According to the Secretary's Advisory Committee on Human Research Protections, these new requirements provide "an opportunity to fundamentally change and improve the consent process and the consent form in human subjects research."

To date, there has been little research focusing on whether the requirements in the Revised Common Rule have helped to make research consent forms more understandable. This study helps build that evidence base by providing the first comprehensive, baseline analysis of the publicly available informed consent forms on ClinicalTrials.gov before January 2019, when the Revised Common Rule took effect. As of that date, there were 763 consent forms used in completed studies available on ClinicalTrials.gov. This study analyzes that data to help determine the common practices and patterns that existed before the Revised Common Rule requirements went into effect. Specifically, this study calculates the overall

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[*] Associate Professor of Law at the University of Arkansas, Little Rock, William H. Bowen School of Law. Trudeau also has a dual appointment with the University of Arkansas for Medical Sciences, where he leads the Regulatory Knowledge & Support Division of the Translational Research Institute. He is also the only lawyer to be appointed to the FDA's Risk Communication Advisory Committee and the National Academies' Roundtable on Health Literacy.

readability of the consents and identifies the individual characteristics of the best and worst consent forms available on the site. The baseline data in this study will be essential to evaluating whether the new consent requirements in the Revised Common Rule have any positive impact on consent forms. Additionally, the takeaways gleaned from this study should help those seeking to further improve consent forms to meet the Revised Common Rule's new understandability requirement.

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I. INTRODUCTION

Did you know that the average U.S. adult reads at around the eighth-grade level?[1] Think about that. We know that 90% of U.S adults over the age of twenty-five complete high school—a number that has been steadily rising for years.[2] So, "[o]ut of the 217 million people age 25 and older, 194 million have a high school diploma or higher."[3] Yet we also know that, from a literacy standpoint, many of those 194 million do not read at the ninth-grade level, let alone at the twelfth-grade level.[4] In the abstract, this disparity may seem inconsequential because, after all, if so many adults can manage to graduate high school with lower reading levels, then they should be able to function well enough to be productive members of society. But this is not usually the case. The limited literacy skills of many of these adults impact them, and society as a whole, in many significant ways.[5]

A person's health is probably the most significant thing impacted by their literacy skills. Did you know that a person's literacy is one of the strongest predictors of a person's health status?[6] Most people, even doctors, are surprised to learn this.[7] What is even more surprising is that all of the studies that have looked at the issue have found that a person's health literacy "is a stronger predictor of an individual's health status than age, income, employment status, education level, and racial or ethnic group."[8]

Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make

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1. Adam E. M. Eltorai et al., *Most American Academy of Orthopaedic Surgeons' Online Patient Education Material Exceeds Average Patient Reading Level*, 473 CLINICAL ORTHOPAEDICS & RELATED RSCH. 1181, 1181 (2015); Elizabeth H. Winslow & Paula Hagan, *Making Research Consent Forms More Readable*, TEX. TECH UNIV. HEALTH SCI. CTR. (2003), https://elpaso.ttuhsc.edu/research/committees/irb/_documents/Making%20Research%20Consent%20Forms%20More%20Readable.pdf.

2. Press Release, U.S. Census Bureau, High School Completion Rate is Highest in U.S. History (Dec. 14, 2017), https://www.census.gov/newsroom/press-releases/2017/educational-attainment-2017.html.

3. *See id.*

4. *Id.* For international readers, most U.S. students must pass twelve grades to graduate high school, after which they can pursue university degrees.

5. *See* BARRY D. WEISS, HEALTH LITERACY: A MANUAL FOR CLINICIANS 11 (2003) [hereinafter HEALTH LITERACY].

6. *Id.*

7. BARRY D. WEISS, HEALTH LITERACY AND PATIENT SAFETY: HELP PATIENTS UNDERSTAND. MANUAL FOR CLINICIANS 17 (2d ed. 2007) [hereinafter HELP PATIENTS UNDERSTAND].

8. U.S. DEP'T OF HEALTH & HUM. SERVS., NATIONAL ACTION PLAN TO IMPROVE HEALTH LITERACY, at iii (2010), https://health.gov/our-work/health-literacy/national-action-plan-improve-health-literacy [hereinafter NATIONAL ACTION PLAN].

appropriate health decisions."[9] A person's health literacy is typically measured by the ability to understand and perform certain tasks, which is not necessarily the same as a person's ability to read at a certain grade level.[10] That is where the numbers get even more troubling. Only 12% of U.S. adults have proficient health literacy skills.[11] A person with a "proficient" level of health literacy "can read and understand lengthy complex written material and synthesize the information to make complex inferences. They can analyze, integrate, and synthesize information in complex documents."[12] What is troubling about this is that the healthcare system often asks people to operate at this "proficient" level by deciphering complex documents and making complex inferences—think about signing up for health insurance, seeking reimbursement from an insurance carrier, understanding treatment options and risks, or interpreting a research consent form, the subject of this article. The system places these burdens on people knowing that 88% of them are going to struggle to perform those tasks.

For a poignant example, consider the following from a then high-school graduate, Toni Cordell (she's now a college graduate and health literacy advocate), which was captured in a health literacy video created by the American Medical Association:

> At approximately 30 or 31, I went into the gynecologist and complained about part of "this" not working correctly and he said we can repair that. Great! I didn't ask all the right questions. When I showed up two weeks later at the admissions office at the hospital, they put enough papers in front of me - I bet there were five papers that I needed to sign. Well, I wasn't going to say excuse me, but I don't read really well, and I certainly don't read fast; I'm concerned with some of these words. To me it was lines and circles over sheets and sheets and sheets, and I wasn't going to reveal my sense of stupidity. So I signed everywhere they told me to sign. Never read it. And then a couple weeks later in the follow-up office visit, the nurse said, "How are you feeling since your hysterectomy?"

9. *Id.*

10. *See* HELP PATIENTS UNDERSTAND, *supra* note 17, at 17.

11. MARK KUTNER ET AL., THE HEALTH LITERACY OF AMERICA'S ADULTS: RESULTS FROM THE 2003 NATIONAL ASSESSMENT OF ADULT LITERACY, at v (2006).

12. Carolyn Crane Cutilli & Ian M. Bennett, *Understanding the Health Literacy of America: Results of the National Assessment of Adult Literacy*, 28 ORTHOPEDIC NURSING 27, 29–30 (2009).

> Now I acted as normal as I could. Inside, my mouth fell open, and I thought to myself, "How could I be so stupid as to allow somebody to take part of my body and I didn't know it."[13]

Ms. Cordell's story, and those like hers, have become the impetus for many advancements in health communication, in clinical practice, in human-subjects research, and in health law and policy.[14]

In human-subjects research, limited health literacy can have dire consequences. There are a lot of reasons for these consequences, but one main reason is the therapeutic misconception—that is, a person's failure to understand that medical research is not the same as medical treatment.[15] Many patients, particularly terminally ill patients, turn to experimental treatments when standard treatment options fail.[16] But what many fail to understand is that, in this context, they are not patients of the researchers, who often are doctors; they are research participants.[17] The experimental treatments they agree to undergo are not necessarily intended to benefit them—they are intended to benefit others like them in the future.[18]

Two elements further compound the problem: (1) a person's health literacy skills and (2) the burdens researchers place on potential research participants.[19] Researchers place the most burdens on participants in the informed consent process, which includes both the written consent form and the verbal discourse that occurs before a participant is enrolled in the study.[20] For example, consider the emotional

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13. Johns Hopkins - AI, *AMA Health Literacy Video - Short Version*, YOUTUBE (Aug. 23, 2012), https://www.youtube.com/watch?v=ubPkdpGHWAQ (transcript of Toni Cordell's portion of the video begins at the 2:45 mark).

14. *See generally* Christopher Trudeau, *Health Literacy's Impact on Health Law & Policy*, *in* HEALTH LITERACY IN CLINICAL PRACTICE AND PUBLIC HEALTH: NEW INITIATIVES AND LESSONS LEARNED AT THE INTERSECTION WITH OTHER DISCIPLINES (R.A. Logan & E.L. Siegel eds., 2020) (discussing health literacy's impact on health law and policy over the past two decades).

15. Gail E. Henderson et al., *Clinical Trials and Medical Care: Defining the Therapeutic Misconception*, 4 PLOS MED. 1735, 1735 (2007).

16. *See generally Right to Try*, FDA (Jan. 14, 2020), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try.

17. People often use the term research subjects or human subjects, but the author thinks that the term "subjects" dehumanizes those who volunteer their time and—in some studies—risk their lives to help others in the future. Because of this, the author will use the widely accepted term "participants" in this article but will use the term "human subjects research" to refer to the overall category of research.

18. Henderson, *supra* note 18, at 1736–37.

19. *See* NATIONAL ACTION PLAN, *supra* note 8, at 12.

20. AGENCY FOR HEALTHCARE RSCH. & QUALITY, INFORMED CONSENT AND AUTHORIZATION TOOLKIT FOR MINIMAL RISK RESEARCH 5–8 (2009) https://www.ahrq.gov/sites/default/files/publications2/files/ictoolkit.pdf.

burdens and literacy burdens placed on this cancer patient who exhausted all her normal treatment options and was offered an experimental therapy.

> "By that point, I had told my husband, 'If this doesn't work, I don't know how much more I can take[.]'" . . . [She was then given] an informed-consent release that listed all the possible side effects. "It was pages and pages of this could happen to you and that could happen to you. I didn't read one page. I just signed at the bottom and said, 'Give it to me.'"[21]

To be sure, since the Nuremberg Code was developed after World War II, there have been legal and ethical protections for research participants. Although from a consent standpoint, we have long known that potential research participants struggle to understand consent. For example, consider this, which was first published in the Journal of the American Medical Association in 1966:

> The reality is that informed consent is often exceedingly difficult or impossible to obtain in any complete sense. The difficulties inherent in this complex situation are no excuse for giving up the effort: informed consent is a goal toward which we strive.[22]

Over the decades, various ethical codes, state laws, and federal regulations were developed to better protect research participants in numerous ways.[23] On a federal level, these protections eventually resulted in the Common Rule, which is the most impactful federal regulation to govern institutional practices when conducting human-subjects research.[24] The original version of the Common Rule was enacted as a federal regulation in 1991 and required those receiving federal funding to adhere to the requirements of the Common Rule.[25] From a consent standpoint, the original Common Rule set out to ensure that participants were informed of key things they needed to know before joining the study.[26] This amounted to eight required elements of consent and up to six additional elements needed depending on the study.[27]

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21. Jerome Groopman, *The T-Cell Army*, NEW YORKER (Apr. 23, 2012), https://www.newyorker.com/magazine/2012/04/23/the-t-cell-army (quoting melanoma patient Sharon Blevin).

22. Henry K. Beecher, *Consent in Clinical Experimentation: Myth and Reality*, 195 JAMA 124, 124 (1966).

23. *See* Alexander Morgan Capron, *Where Did Informed Consent for Research Come From?* 46 J.L. MED. & ETHICS 12, 15 (2018).

24. *Id.* at 22.

25. *Id.*

26. Leah L. LeCompte & Sylvia J. Young, *Revised Common Rule Changes to the Consent Process and Consent Form*, 20 OCHSNER J. 62, 62 (2020).

27. *Id.* at 63–64.

Though the original Common Rule added much needed protection for research participants, over the years, "consent forms . . . evolved to protect institutions rather than to provide potential research subjects with some of the most important pieces of information that a person would need in order to make an informed decision about whether to enroll in a research study."[28] Since the original Common Rule was enacted, many studies have measured the readability of research consent across all areas of scientific research.[29] Those studies have routinely found that consent forms are typically written at too high of a reading level, with few written at or below the eighth-grade reading level making them understandable for those with average literacy skills.[30] Moreover, numerous studies have focused on what features help make consent forms understandable—things like word choice, short sentences, clear graphic design elements, and ample white space.[31] As a result, researchers and "institutional review boards (IRBs) have been aware of these problems for many years and have taken some steps to abate them, [yet] little progress has been made in making consent documents easier to understand."[32]

In an attempt to remedy this and to account for technological advances in research and genetics, not to mention the creation of the internet, the Department of Health and Human Services and the Food and Drug Administration began the rulemaking process in 2011 leading to major revisions in the Common Rule.[33] Many of these revisions began being enforced on January 21, 2019.[34] The Revised Common Rule kept the same eight required elements for consent and six "as

28. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,969–70 (proposed Sept. 8, 2015) (to be codified at 49 C.F.R. pt. 11).

29. *See, e.g.*, S. Michael Sharp, *Consent Documents for Oncology Trials: Does Anybody Read These Things?*, 27 AM. J. CLINICAL ONCOLOGY 570 (2004); Paul P. Christopher et al., *Consent Form Readability and Educational Levels of Potential Participants in Mental Health Research*, 58 PSYCHIATRIC SERVS. 227 (2007); Véronique Ménoni et al., *The Readability of Information and Consent Forms in Clinical Research in France,* 5 PLOS ONE 1 (2010).

30. *See* Sharp, *supra* note 29, at 573–74; Kristie Hadden et al., *Improving Readability of Informed Consents for Research at an Academic Medical Institution*, 1 J. CLINICAL & TRANSLATIONAL SCI. 361 (2017).

31. *See generally* Adam Nishimura et al., *Improving Understanding in the Research Informed Consent Process: A Systematic Review of 54 Interventions Tested in Randomized Control Trials*, 14 BMC MED. ETHICS, no. 28, 2013, at 1 (discussing various methods past studies have used to improve understanding).

32. David B. Resnick, Do Informed Consent Documents Matter?, 30 CONTEMP. CLINICAL TRIALS 114, 114 (2009).

33. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,512–21 (July 26, 2011).

34. Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period, 83 Fed. Reg. 28,497 (June 19, 2018). The final rule was passed in June 2018, but the consent requirements did not become mandatory until January 21, 2019. *Id.*

needed" elements, but added one additional mandatory element to help address the rise of biospecimen research and added up to three "as needed" elements that fill much needed information gaps that arose from past problems and advances in genetic research, among other things.[35] The chart below summarizes the original requirements and the newly added requirements in the Revised Common Rule:[36]

Revised Common Rule Requirements	
Basic Requirements	**As Needed Requirements**
1. Purpose and explanation of the research	10. If there are unknown or unforeseeable risks
2. Risks & foreseeable discomforts	11. If and when involuntary removal from study is possible
3. Benefits (to person & others)	12. Additional costs that may be expected by participating
4. Alternatives that might also help the participant	13. Consequences of early withdrawal from study
5. Extent confidentiality will be maintained	14. If significant findings will be provided
6. Compensation & treatment available if complications	15. Approximate number of people in the study
7. Contact info for questions about research	16. *[new]* If clinically relevant research results will be disclosed and under what conditions
8. That participation is voluntary and there will be no loss of benefits if the participant declines	17. *[new]* If biospecimens might be used for commercial profits—even if identifiers are removed
9. *[new]* One of these: The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed; OR That identifiers might be removed and the de-identified information or biospecimens will be used for future research without additional informed consent.	18. *[new]* If biospecimens research, whether research will or might include whole genome sequencing

Chart 1. Revised Common Rule Requirements.

From a literacy standpoint, the Revised Common Rule took major steps to address the known problem that people struggle to understand consent forms. To

35. *See* 45 C.F.R. § 46.116(b)–(c) (2018).

36. For the exact wording of each requirement, see 45 C.F.R. § 46.116(b)–(c) (2018).

help make consent forms understandable to the masses, the Revised Common Rule requires the following:

(1) That "[t]he information that is given to the subject . . . be in language understandable to the subject . . . ."[37]

(2) That the participant "be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, *and* an opportunity to discuss that information."[38]

(3) That "consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject . . . in understanding the reasons why one might or might not want to participate in the research."[39]

Additionally, the revised rule requires that "[i]nformed consent as a whole . . . be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's . . . understanding of the reasons why one might or might not want to participate."[40] These added protections are steps in the right direction and offer a "significant opportunity to make the informed consent process better for research subjects."[41] Despite these participant-friendly requirements, the increase in the number of mandatory and "as needed" elements along with the key information requirement will make consent forms longer. But the goal "is to create more understandable consent forms, not to shorten or lengthen consent forms."[42] Length, of course, can add to the participant's burden, but if the overall form is easier to navigate and understand, this should yield positive results, despite the increased length.

Importantly, the question that remains unanswered is whether the changes in the Revised Common Rule have had (and will have) any impact on the readability and understandability of informed consent forms. That is the question that this study helps to answer.

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37. *Id.* § 46.116(a)(3).

38. *Id.* § 46.116(a)(4) (emphasis added).

39. *Id.* § 46.116(a)(5)(i).

40. *Id.* § 46.116(a)(5)(ii).

41. Sec'y's Advisory Comm. on Hum. Rsch. Prots., *Attachment C -New "Key Information" Informed Consent Requirements*, HHS.GOV (Oct. 17, 2018), https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-november-13-2018/index.html#:~:text=SACHRP%20believes%20that%20it%20is,making%20from%20the%20subject's%20perspective.

42. *Id.*

II. ABOUT THIS STUDY

This study conducts textual and readability analyses of the research consent forms publicly available on ClinicalTrials.gov. The goal is to determine just how challenging these consent forms might be for participants to understand. In truth, this is a two-part study. Part One, the subject of this article, performs a secondary data analysis of the available consent forms on ClinicalTrials.gov in the years before the Revised Common Rule took effect. This is essential so that there is baseline data that "provides a clear starting point to benchmark progress against. Without something to measure new results against, it is difficult to assess results as positive, negative or otherwise."[43]

Part Two of the study, the subject of a future article, will use the baseline data from this article to compare it against the consent forms submitted to ClinicalTrials.gov since the Revised Common Rule took effect in January 2019. The baseline data in this article will help determine if the new consent requirements have had any positive impact on the readability and understandability of consent forms. In the end, both parts will form a cohesive whole that will help guide researchers, research institutions, institutional review boards, and government agencies in further advancing the goal of creating consents that facilitate "understanding of the reasons why one might or might not want to participate in the research."[44]

A. The Dataset on ClinicalTrials.gov

Both parts of this study were borne out of conversations with then Acting Director of ClinicalTrials.gov, Dr. Rebecca Williams. During those conversations, Director Williams stated that there were all sorts of unexplored data on ClinicalTrials.gov that might prove useful in helping to improve the understandability of informed consent forms.[45] This is certainly the case, as there are nearly 3,000 consent forms publicly available on the site as of February 2021, and this number is increasing every week.[46] These publicly available consent forms create the dataset for both parts of this study.

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43. Kayla Ferguson, *How to Design a Great Baseline Survey,* HUMS. OF DATA (May 11, 2017), https://humansofdata.atlan.com/2017/05/design-great-baseline-survey/.

44. *See* Sec'y's Advisory Comm. on Hum. Rsch. Prots, *supra* note 41; *see also* 45 C.F.R. § 46.116.

45. Interview with Dr. Rebecca Williams, Acting Director, ClinicalTrials.gov (Dec. 4, 2019).

46. U.S. Nat'l Libr. of Med., *ClinicalTrials.gov Background,* CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/about-site/background (last visited Feb. 26, 2021) [hereinafter *ClinicalTrials.gov Background*].

As background, ClinicalTrials.gov was first made available to the public in February 2000.[47] It was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA).[48] The Act required the National Institutes of Health (NIH) "to establish a registry of clinical trials information for both federally and privately funded trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for serious or life-threatening diseases or conditions."[49] Since its creation, ClinicalTrials.gov has become the primary repository for information about medical studies that involve human participants.[50] As the name suggests, most of these studies are clinical trials, which are studies where "human volunteers are assigned to interventions (for example, a medical product, behavior, or procedure) based on a protocol (or plan) and are then evaluated for effects on biomedical or health outcomes."[51] But the site "also contains records describing observational studies and programs providing access to investigational drugs outside of clinical trials . . . ."[52]

From a research standpoint, the breadth of this information provides the perfect opportunity to measure the consent forms submitted for studies both before and after the Revised Common Rule took effect. Notably, however, "ClinicalTrials.gov does not contain information about all the clinical studies conducted in the United States because not all studies are required by law to be registered . . . ."[53] Only "applicable clinical trials" are required to post information to ClinicalTrials.gov.[54] These include interventional studies of FDA-regulated drugs, biologics, or device products when the study (1) "has one or more sites in the United States," (2) "is conducted under an FDA investigational new drug application," or (3) "involves a drug, biological, or device product that is manufactured in the United States . . . and is exported for research."[55]

Since not all scientific research (or even all clinical trials) must be posted on the site, this creates the first limitation of this study: selective deposit bias. Selective

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47. *Id.*

48. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified at 21 U.S.C. §§ 301–392). The FDAMA of 1997 was the first major overhaul of the Food, Drug, and Cosmetic Act of 1938. *See Food and Drug Administration Modernization Act (FDAMA) of 1997*, FDA (Mar. 29, 2018), https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-modernization-act-fdama-1997.

49. *See ClinicalTrials.gov Background*, *supra* note 46.

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.*

54. U.S. Nat'l Libr. of Med., *FDAAA 801 and the Final Rule*, CLINICALTRIALS.GOV, https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa (last visited Feb. 26, 2021).

55. *Id.*

deposit bias occurs when not all data is recorded to a dataset.[56] Or, to put it another way, the results of the consents that are included in the public dataset are impacted by those not included in it.[57] The selectivity of submissions to ClinicalTrials.gov will be more significant for this part of the study—that is, for those consent forms submitted before the Revised Common Rule took effect. This is because the Final Rule for Clinical Trials Registration and Results Information Submission did not become effective until January 2017.[58] The Final Rule clarified and expanded the submission requirements that were first promulgated in Section 801 of the Food and Drug Amendments Act of 2007.[59] As a result, the submissions that occurred before the Final Rule took effect were voluntary and were either driven by the policies and practices of the sponsors and research institutions conducting the studies or by specific funding requirements.[60] Yet, as will be further explained in the next section, there were hundreds of studies that had uploaded consent forms, from all phases of clinical trials, submitted to ClinicalTrials.gov before the Final Rule and the Revised Common Rule took effect.[61] This minimizes the impact of any selective deposit bias.

B. Extracting & Creating the Sample from the ClinicalTrials.gov Dataset

ClinicalTrials.gov offers advanced search features allowing a person to search for particular types of studies.[62] You can search by keywords or by study criteria, such as phase of study, completed studies, studies that include results, etc.[63] In September 2020, I used ClinicalTrials.gov's advanced search features to derive the specific dataset for this study.[64] Since the goal of this study was to limit the results to consent forms used before the Revised Common Rule took effect, I limited the search to those studies that included informed consent forms and had reached "Primary Completion" status by January 18, 2019, the Friday before the Revised Common Rule took effect, which fell on the following Monday. I further limited the search results to return only studies targeting adults (ages 18–65 and 65+), as

56. ROBERT M. LAWLESS ET AL., EMPIRICAL METHODS IN LAW 127 (1st ed. 2010).

57. *See id.*

58. Clinical Trials Registration and Results Information Submission, 81 Fed. Reg. 64,982 (Sept. 21, 2016) (to be codified at 42 C.F.R. pt. 11).

59. *Id.*

60. *Id.* at 64,985–86 (discussing the background for the final rule and how certain clinical trials were selectively submitted before it).

61. *See supra* note 45.

62. U.S. Nat'l Libr. of Med., *Advanced Search*, CLINICAL TRIALS.GOV, https://www.clinicaltrials.gov/ct2/search/advanced?cond=&term=&cntry=&state=&city=&dist= (last visited Sept. 12, 2020).

63. *Id.*

64. Specifically, I ran the search on Saturday, September 12, 2020, at 8:58 PM.

research with minors usually involves both assent by the minor and consent by a parent or guardian.[65]

This advanced search yielded 763 studies that included consent forms and met the other parameters.[66] At that point, I extracted the results into a spreadsheet, which included weblinks to the various study materials available, such as the study protocol, the results (if any), and any informed consent forms that researchers uploaded to ClinicalTrials.gov. After extracting these results, I set about reviewing all 763 consent forms, fully intending on scoring each one using the methods described in the sections below. However, after initially reviewing each one, I ended up excluding over 300 results for one or more of the following reasons.

First, while I knew that all the files uploaded to ClinicalTrials.gov were PDFs (portable data files), many of them were "photo" PDFs—especially those that were uploaded before PDF creation became much easier to accomplish. The problem with these "photo" PDFs was that they could not be scored using computerized readability measurement tools. Similarly, other consents had to be excluded because they included heavy redactions or watermarks that made them unreadable by these same readability measurement tools.[67]

Another problem that was more infrequent, but still prevalent enough to mention, was that a consent form was not uploaded with the study documents for some studies, despite the submission indicating that one was included. This, of course, led to exclusion of those results since the purpose of this study was to measure the consent form. Finally, while I was reviewing each consent form before measuring it, I consciously decided to exclude consent forms from foreign-based studies that did not have consent forms that included the requirements mandated by the Common Rule. I did this to ensure that the data measurement was consistent among the forms, as some of these forms were more akin to one-page clinical consents than research consents that included the mandatory and "as needed" requirements. Nevertheless, I did measure those foreign-based consents that included information on the topics required by the Common Rule, which largely amounted to consents from Canada and the United Kingdom.

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65. For a discussion of consent and assent in research with children, see generally INSTITUTE OF MEDICINE (US) COMMITTEE ON CLINICAL RESEARCH INVOLVING CHILDREN, *Understanding and Agreeing to Children's Participation in Clinical Research, in* ETHICAL CONDUCT OF CLINICAL RESEARCH INVOLVING CHILDREN (Marilyn J. Field & Richard E. Behrman eds., 2004).

66. *Supra* note 64.

67. Of course, it is possible to calculate readability scores by hand, but that lends itself to mathematical errors and was logistically difficult given the hundreds of consent forms I was looking to measure.

In total, the study calculates results for 427 consent forms out of the 763 results returned by the advanced search—a 56% results rate.

III. MEASURING THE CONSENT FORMS

Determining what to measure and how to measure it was a key part of my preliminary research. Measuring understandability on a mass scale is not very practical, as understandability is individualistic. The best way to measure whether people understand a consent form is to test it with them—that is, to conduct focus groups with people from your target population or use other usability testing techniques.[68] But doing so for 427 consent forms that have already been used with research participants was not feasible. Because of similar logistical problems faced in other contexts, researchers have often used readability formulas as a proxy for understandability.[69] Of course, "understanding is a complex process and is influenced by many intertwined variables," such as a person's familiarity with the subject matter, the design and layout of the written material, and the person's current mental and emotional state.[70] Nevertheless, a "poor score is a red flag that the document was probably developed without a focus on users, without any consideration of who the users are, what they know, how it should be organized for them, etc. . . ."[71] As such, these readability scores—both good and bad—are "quick indicators to assist writers in targeting information to the lay public."[72]

Because of this, using readability metrics aligned well with the purpose of this study—to help indicate whether a consent form is likely to be understood by the average adult research participant. Additionally, using such metrics normalizes the comparisons for both parts of this study and for other similar studies. That is, using the same metrics and measuring techniques for both the Pre-Revised Common Rule consent forms and the Post-Revised Common Rule consent forms will help the results be more comparable to each other.

A. Readability Formulas

To measure the consent forms, this study uses two related readability formulas: the Flesch "Reading Ease" Formula and the Flesch–Kincaid "Grade-Level"

68. *See* Janice Redish, *Readability Formulas Have Even More Limitations Than Klare Discusses*, 24 ACM J. COMPUT. DOCUMENTATION 132 (2000) (discussing the benefits of usability testing as opposed to readability testing).

69. *See, e.g.*, Pranay Jindal & Joy C. MacDermid, *Assessing Reading Levels of Health Information: Uses and Limitations of Flesch Formula*, 30 EDUC. FOR HEALTH 84 (2017).

70. *Id.* at 86.

71. *See* Redish, *supra* note 68, at 136.

72. *See* Jindal & MacDermid, *supra* note 69, at 86.

Formula. There are many other readability measures available, but these two have been widely used and have been validated against other readability and comprehension measures.[73] Additionally, both readability measures have been around for decades. In fact, Rudolph Flesch first wrote about his "reading ease" formula in 1948.[74] Here is how Flesch himself describes the formula: "It measures the average sentence length in words and the average word length in syllables. You put these two numbers into an equation and get a number between 0 and 100 that shows you the difficulty of your piece of writing."[75] Here is the specific formula: "Multiply the average sentence length by 1.015. Multiply the average word length by 84.6. Add the two numbers. Subtract this sum from 206.835. The balance is your readability score."[76]

Flesch developed this measure because the formulas in use at the time only measured words, so his formula was based on how "the human mind works."[77] Flesch validated this formula long ago—it was the subject of his PhD thesis at Columbia University.[78] He explains why the two measurements—sentence length and word choice—work well together:

> When you read a passage, your eyes and mind focus on successive points on the page. Each time this happens, you form a tentative judgment of what the words mean *up to that point.* Only when you get to a major punctuation mark—a period, a colon, a paragraph break—does your mind stop for a split second, sum up what it has taken in so far, and arrive at a final meaning of the sentence or paragraph. The longer the sentence, the more ideas your mind has to hold in suspense until its final decision on what all the words mean *together.* Longer sentences are more likely to be complex—more subordinate clauses, more prepositional phrases and so on. That means more mental work for the reader. So the longer a sentence, the harder it is to read.

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73. For a general discussion of the other measures that these formulas have been validated against, see Jindal & MacDermid, *supra* note 69, at 85.

74. Rudolf Flesch, *A New Readability Yardstick*, 32 J. APPLIED PSYCH. 221 (1948) [hereinafter *New Readability Yardstick*].

75. RUDOLF FLESCH, *Let's Start With the Formula, in* HOW TO WRITE PLAIN ENGLISH: A BOOK FOR LAWYERS AND CONSUMERS 1 (1979) (archived from the original in 2016 at https://web.archive.org/web/20160712094308/http://www.mang.canterbury.ac.nz/writing_guide/writing/flesch.shtml) [hereinafter HOW TO WRITE PLAIN ENGLISH].

76. *Id.*

77. *Id.*

78. Edwin L. Batistella, *Reading, Writing, and Readibility – Appreciating Rudolph Felsch*, OUPBLOG (Oct. 6, 2019), https://blog.oup.com/2019/10/reading-writing-and-readability-appreciating-rudolph-flesch/.

> Exactly the same thing is true of words. Some words are short and simple, others are long and complex. The complexity shows up in the prefixes and suffixes. *Take* is a simple, short word that doesn't present much difficulty to a reader. But *unmistakably* has the prefixes *un-* and *mis-* and the suffixes *-able* and *-ly* and gives the mind much more to think about than *take*.
>
> In using the formula, you count words and syllables to measure the mental work the reader will have to do.[79]

But what does that score actually mean?

> "With a score of 90 to 100 your writing could be understood by an average 11-year old and a score of 60 to 70 could be understood by average 13 to 15-year olds. A score of zero to 30 means your writing could be understood by a university graduate. The higher the score the easier the writing is to read and comprehend."[80]

Over the years, this formula has become so popular that language advocates have used it to measure the reading ease level of commonly known works. For example, the Harry Potter books have an average reading ease level around 73.[81] Using this formula to measure written documents has even been mandated by statute: Florida requires certain insurance documents to have a Flesch "Reading Ease" score of 45 or higher.[82]

In 1975, over twenty-five years after the "reading ease" formula was developed, Peter Kincaid and his team further developed Flesch's formula for the U.S. Navy.[83] They adjusted the formula to give a grade-level for written material.[84] This formula is called the Flesch–Kincaid Grade Level Formula. Here is how the grade-level

79. HOW TO WRITE PLAIN ENGLISH, *supra* note 75 (emphasis in original).

80. *How Do You Measure Readability?*, FULL MEDIA, https://www.fullmedia.com/how-do-you-measure-readability (last visited Mar. 1, 2021).

81. Sara A. Metwalli, *Five Tips that Make Your Writing Easy to Understand*, MEDIUM (July 11, 2020), https://medium.com/swlh/five-tips-that-make-your-writing-easy-to-understand-c59fa6c6f2d9).

82. FLA. STAT. § 627.4145 (2021).

83. *See* Jindal & MacDermid, *supra* note 69, at 85.

84. *Id.*

score is calculated: Grade Level = .39 (words/sentence) + 11.8 (syllables/word) – 15.59.[85]

Like the "reading ease" formula, this grade-level formula looks at the average number of words in a sentence and the average number of syllables of words in the text.[86] Unlike the "reading ease" formula, this grade-level formula equates the result to grade levels of the U.S. educational system.[87] For example, a grade-level score of 7.1 means that the written material should be understandable to people who have went through at least the equivalent of the seventh grade, first month in the U.S. educational system.[88] As stated at the outset of this article, the average reading level of a U.S. adult is around the eighth grade;[89] this average equates to the Flesch–Kincaid Grade-Level Formula.

Flesch Reading Ease Score	Equated Reading Difficulty	Conversion to Flesch–Kincaid Grade-Level Score
91–100	Very Easy	5th Grade
81–90	Easy	6th Grade
71–80	Fairly Easy	7th Grade
61–70	Average	8th–9th Grade
51–60	Fairly Difficult	10th–12th Grade
31–50	Difficult	13th–16th Grade
0–30	Very Difficult	College Graduate (16+)

Table 1. Readability Score Conversion Table.[90]

Like the "reading ease" formula, this formula has been widely used to score well-known works. For example, those same Harry Potter books that score a 73 using the "reading ease" formula score around the fifth or sixth grade using the grade-level formula.[91] On the opposite end of the spectrum, the Affordable Care Act has a Flesch–Kincaid grade-level score of about 13, meaning it takes someone

85. J. PETER KINCAID ET AL., DERIVATION OF NEW READABILITY FORMULAS (AUTOMATED READABILITY INDEX, FOG COUNT AND FLESCH READING EASE FORMULA) FOR NAVY ENLISTED PERSONNEL 14 (1975).

86. *See* Jindal & MacDermid, *supra* note 69, at 85.

87. *See id.*

88. *See id.*

89. For more details on the results of the 2003 NAAL assessment, see KUTNER ET AL., *supra* note 11.

90. *See* Jindal & MacDermid, *supra* note 69, at 85.

91. *Is Your Content Making the Grade?*, VISIBLE THREAD BLOG (Mar. 2020), https://www.visiblethread.com/2020/03/readability-is-your-content-making-the-grade/.

with the reading skills of a first-year university student to decipher it.[92] That disparity among readability levels for widely read works was a main motivator for this study. Simply put, researchers and IRBs need to understand whether past consent practices give research participants a chance at understanding the forms. A consent form that scores at or below the eighth grade is more likely to be understandable to the average U.S. adult research participant than one with a tenth-grade readability level or higher.

B. Other Measures for this Study

Because of what both formulas can and cannot measure, it was important to include other criteria to help further determine if there are any patterns among the consents that scored well using the readability measures and among those that did not. This study measures the following for each of the 427 consents:

- Flesch–Kincaid Grade Level
- Flesch Reading Ease Level
- Total Word Count
- Percentage of Long Sentences
- Percentage of Passive Sentences

Since sentence length is a key feature of both readability measures, it made sense to calculate the percentage of long sentences in each consent form. For this study, I defined a long sentence as a sentence with more than twenty-five words.[93] "Long sentences mask multiple concepts. Splitting up these sentences will result in a clearer message."[94] Of course, "[l]ong sentences are not a problem just because they are long. Length is only a corollary of several linguistic aspects that make sentences difficult."[95] But, for this study, calculating the percent of long sentences can serve as another proxy for difficulty, especially when combined with the scores from the readability formulas. Relatedly, although the total number of words in a document does not necessarily mean the language is complex or difficult to understand, it also made sense to calculate the number of words in each consent form to see if patterns emerged regarding document length.

Additionally, one of the telltale signs of a document that may be difficult to read is how much passive voice is used throughout. "Passive language is where the

92. *Id.*

93. *See* Sara Vincent, *Sentence Length: Why 25 Words Is Our Limit*, INSIDE GOV.UK (Aug. 14, 2014), https://insidegovuk.blog.gov.uk/2014/08/04/sentence-length-why-25-words-is-our-limit/.

94. VISIBLE THREAD, 2020 ASSET MANAGEMENT CLARITY REPORT 38 (2020), https://www.visiblethread.com/2020-asset-management-clarity-report/.

95. *See* Redish, *supra* note 68, at 136.

subject of a sentence is acted on by the verb."[96] For example, "Your doctor will call you in the morning" is an active sentence, but "You will be called in the morning" is a passive sentence because the actor is not stated—something called an implicit agent. The problem with this type of phrasing—and with passive voice in general—is that passive voice makes it harder for someone to determine who is doing the action—or who is supposed to do what. This can create ambiguity or, at a minimum, confusion that could be easily avoided.[97] Because of this, I calculated the percentage of passive sentences for each scored consent to get a better sense of how prevalent this practice is in research consent forms.

C. Examining the Top- and Bottom-Scoring Forms

After calculating these metrics for all the consent forms, I used the Flesch–Kincaid Grade-Level Score to separate out the forms in two ways. First, I looked at the 100 best-scoring consent forms and the 100 worst-scoring consent forms. I did this to compare the aggregate data from the top 100 to the bottom 100 to look for patterns that might emerge. Second, after comparing the data for the top 100 and bottom 100 forms, I used the grade-level score to separate out the 30 best-scoring forms and the 30 worst-scoring forms. I then took a closer look at those 60 forms, reading through them in detail, looking for a few additional things:

(1) whether the form used question-style headings, which are a widely accepted practice to help aid understanding;[98]

(2) whether it used second-person language (i.e., you) to speak to the reader; and

Additionally, I also looked for patterns in content and writing style that led to the form being scored at a high- or low-grade level. While doing this added a layer of subjectivity to the study, that subjectivity seemed warranted given the limitations that readability metrics have on determining understandability. After all, even if a form scores well using a readability measure, if it is written in 10-point font, includes no white space, and uses abstract headings or impersonal language, then most would not call it easy to read.[99]

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96. VISIBLE THREAD, *supra* note 94, at 38.

97. *See* KENNETH A. ADAMS, A MANUAL OF STYLE FOR CONTRACT DRAFTING 48 (4th ed. 2017) (discussing the drawbacks to passive voice and obscuring the agent in a sentence).

98. *See* Plain Language Action and Info. Network, *Add Useful Headings,* PLAINLANGUAGE.GOV, https://www.plainlanguage.gov/guidelines/organize/add-useful-headings/ (last visited Mar. 3, 2021).

99. *See* Plain Language Action and Info. Network, *Design for Reading,* PLAINLANGUAGE.GOV, https://www.plainlanguage.gov/guidelines/organize/add-useful-headings/ (last visited Mar. 7, 2021) (discussing the various elements that create a clear, user-friendly design).

D. The Measurement Tool for the Study

Before beginning the study, I knew I needed to find a measurement tool that (1) could extract text and measure the readability of PDF documents (most available tools cannot measure PDFs) and (2) could measure other metrics besides readability, like percentage of long sentences and passive voice. This led me to Visible Thread, a company whose "mission is to make business communications clearer [and] more transparent, leading to better business outcomes."[100] Visible Thread has developed a product called VT Writer, which can analyze "MS Word Docs, PDFs and Raw Text for plain language and complex, jargon-laden copy" and flag complex sentences that are overly long, overly passive, or use jargon that makes them hard to read.[101] After deciding that this would be a viable product to use for this study, I contacted Visible Thread, who graciously agreed to grant me free, unrestricted access to VT Writer for research purposes. I used VT Writer to score and measure the 427 consent forms for five metrics: (1) grade level, (2) reading ease, (3) total number of words, (4) percentage of long sentences, and (5) percentage of passive sentences. Unfortunately, as mentioned previously, the tool was unable to measure those consent forms that were "photo" PDFs or that contained extensive redacting or watermarks, so I excluded them from the study. However, given the relative difficulty of altering, changing, or extracting data from PDFs, I doubt that any widely available computer scoring tool can effectively do so.

To calculate the Flesch Reading Ease and Flesch–Kincaid Grade-Level Scores, VT Writer uses the formulas listed above that focus on sentence length and syllables of the words used. Additionally, to calculate the percentage of long sentences, VT Writer measures "the proportion of sentences that are longer than 25 words."[102] Specifically, the formula VT Writer uses to determine this is: Long Sentences divided by Total Sentences multiplied by 100.[103] When measuring passive sentence percentage, VT Writer looks for "the proportion of sentences containing passive voice."[104] The formula VT Writer uses to determine this is: Passive Sentences divided by Total Sentences multiplied by 100.[105]

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100. *About Visible Thread*, VISIBLETHREAD, https://www.visiblethread.com/about-us/ (last visited Mar. 1, 2021).

101. *VT Writer*, VISIBLETHREAD, https://www.visiblethread.com/vt-writer/ (last visited Mar. 1, 2021).

102. *See* VISIBLE THREAD, *supra* note 94, at 38.

103. *Id.*

104. *Id.*

105. *Id.*

E. A Caveat About Computerized Readability Scoring

Before turning to the results of the study, I would be remiss if I failed to point out a major caveat to the study—the way computerized calculators score materials can vary widely due to how the particular program counts syllables, punctuation marks, etc.[106]

> Differences in word and syllable counts [can] result[] from the way hyphens, contractions, digits, dates, acronyms, abbreviations, and other text elements were treated. This problem occurs because the way that the number of words, syllables, and sentences is to be determined is sometimes vague and the rules used to count them vary between equations. There are no universal counting rules, at least for these equations.[107]

This limitation, of course, is still present when hand scoring documents though because how the scorer interprets syllables, sentence breaks, etc., can impact the result.

The other notable limitation with computerized scoring is that to be more accurate, the to-be-scored documents should be "prepared" before being scored.[108] This means that before scoring, the scorer should remove periods, formula, references, titles, and other aspects of documents that might impact the scoring. For example, some computer programs may interpret the period in "Dr." as the end of a sentence, thereby reducing the readability score because of that short sentence. On the other hand, preparing documents is often variable, and scorer specific, and it can lead to removing elements that "are important to understanding each document."[109] For this study, I did not prepare each document before I scored them with VT Writer. This was largely because each of the consents were pdf documents and altering them proved quite difficult. When I altered some of the documents in an attempt to "prepare" them, those alterations impacted whether the altered pdf could be scored in VT Writer. On a couple of occasions, the original was able to be scored but the altered version returned errors. Conversely, there was a benefit to not "preparing" the documents before scoring them. Scoring every document using the same computer-scoring method helps ensure that every document is put through the

106. *See* Shixiang Zhou et al., *How Consistent Are the Best-Known Readability Equations in Estimating the Readability of Design Standards?*, 60 IEEE TRANSACTIONS ON PRO. COMMC'N 97, 108–09 (2017).

107. *Id.* at 108.

108. *Id.* at 109.

109. *Id.*

same standards (however flawed), which helps create consistency among the scores for this study and for future studies measuring consent forms.[110]

With that caveat aside, the results below still help set a baseline for research consents submitted to ClinicalTrials.gov before the Revised Common Rule took effect.

IV. Overall Results

As mentioned above, the overall results for this study include scored results for 427 of the 763 consent forms available on ClinicalTrials.gov that met the search parameters—a 56% scoring rate.

The average Flesch–Kincaid grade-level score for the forms scored was 9.37, with a median score of 9.4. That means that the average consent form reads at the early high school reading level. These scores were lower than I anticipated based on past studies, but well above the recommended eighth-grade level. These lower-than-expected scores are likely due to not "preparing" the documents before scoring, as noted in the section above. Notably, only 12.1% (n=52) fell below the recommended 8.0 reading level. Even if we increase that recommended range up to 8.9, only 39.8% (n=170) of the consent forms fell below the 9.0 Flesch–Kincaid Grade Level. What that means, of course, is that the remaining 60% of the forms (n=257) were above the reading level that might make them understandable to the average U.S. adult research participant.

Grade-Level Range	Number of Forms in Range	Percent of All Forms (n=427 forms)
Below 8.0	52	12.1%
Below 8.9	170	39.8%
9.0 +	257	60.0%

Table 2. Number of Consents by Grade-Level Range.

Interestingly, there was great variability in the grade levels based on the particular consent form. The best performing consent scored at the 5.4 grade level, and the worst performing consent form scored at the 14.1 grade level, which is equivalent to the sophomore in college level. This is nearly a 9 grade-level difference, which shows just how variable consent forms can be based on the skills, abilities, and motivations of those who are writing and approving the consent form.

110. If other researchers conduct future studies, the methods they use to "prepare" a document may be different than those I subjectively used if I were to "prepare" the documents before scoring these forms.

What's more, this variance was not attributable to the risk level or difficulty level of either study; the best scoring form was for a phase 3 clinical trial[111] and the worst performing form involved an osteopathic manipulation treatment.[112]

Turning to the Flesch Reading Ease scores, the average score for all scored forms was 51.7, with a median score of 52. This equates to the average consent language being on the border of "fairly difficult" or "difficult" to read based on the score conversion chart in Table 1 above. For both readability measures, both the best scoring consent and the worst scoring consent were the same forms. The best had a "reading ease" score of 70, which puts it on par with the readability level of Harry Potter books. But the worst consent had a "reading ease" score of a 32, meaning that, if it were an insurance form, it would not come close to meeting the readability standard mandated by the recent Florida statute that requires a reading ease score of at least 45.[113]

What is interesting about the aggregate metrics is the slight variance between the average grade-level scores and the average "reading ease" scores. A Flesch–Kincaid Grade-Level score of a 9.37 is supposed to equate to a "reading ease" score in the low 60s, yet the average Flesch Reading Ease Score was a 51. This would suggest that the grade-level scores should be in the 10–11 range, not the 9–10 range. But variance among readability scoring metrics is common[114] and this variance is minimal. Plus, both measures show that the average form still falls well outside of the recommended readability range.

In any case, these overall results show that researchers still have room to improve consent forms to make them more understandable to the average research participant. What's both heartening and troubling is the wide disparity among the best and the worst forms. On one hand, it shows that many are not valuing the way information is presented to their potential research participants. It suggests that the consent may have been an afterthought, or at least a low priority, despite that it has long been known that many struggle to understand consent forms. But, on the other hand, the variance also shows that consents can be, and have been, created well.

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111. A TRIAL OF VITAMINS AND HAART IN HIV DISEASE PROGRESSION STUDY CONSENT FORM (2006), https://clinicaltrials.gov/ProvidedDocs/69/NCT00383669/ICF_000.pdf.

112. KAREN T. SNIDER ET AL., ULTRASONOGRAPHIC EVALUATION OF THE EFFECT OF OSTEOPATHIC MANIPULATIVE TREATMENT ON SACRAL BASE ASYMMETRY (2019), https://ClinicalTrials.gov/ProvidedDocs/01/NCT02820701/ICF_001.pdf.

113. *See* FLA. STAT. § 627.4145 (2021).

114. Lih-Wern Wang et al., *Assessing Readability Formula Differences with Written Health Information Materials: Application, Results, and Recommendations*, 9 RSCH. SOC. & ADMIN. PHARMACY 503 (2013).

This is heartening because it shows that consents can be improved if care and effort is taken in creating the forms—that this is a skill that can be learned and nurtured.

Overall Results for the Other Metrics

As mentioned earlier, the readability metrics do not truly measure understandability of consent forms. But we can derive more clues about this by looking at other metrics, like the percentage of long sentences in a document and the percentage of passive voice. Overall, 26% of the average consent form scored contained long sentences, with the median percentage of long sentences in a form being 25.9%. That means that over a quarter of a typical consent form was written using sentences longer than 25 words. The disparity, again, was wide between the best scoring form and the worst scoring form. Only 7.54% of the best scoring form used long sentences,[115] while 54.84% of the worst scoring form contained long sentences.[116]

As for percentage of passive voice, the average form used the passive voice 23.36% of the time. The median percentage of passive voice was 23.1%. Again, there was a wide disparity between the best and the worst form. The best scoring consent contained only 10.33% passive voice,[117] but the worst used 42.54% passive-voice phrasing.[118] Additionally, there were a handful of other consents with passive-voice percentages around that range.[119]

Lastly, to get a sense for the time commitment needed to read through the entirety of a consent form, I calculated the word length for each form. The average word length for all 427 consent forms was 3,602 words, while the median word length was 3,150 words. This divergent median was due to a couple of factors that led to some really long consent forms that increased the mean. First, some studies

115. TEX. TECH UNIV., *Informed Consent Form, in* DETERMINING DIETARY PATTERN ACCOMPANYING EGG INTAKE USING REMOTE FOOD PHOTOGRAPHY METHOD 27, 27–32 (2018), https://clinicaltrials.gov/ProvidedDocs/00/NCT03404700/Prot_SAP_ICF_002.pdf.

116. SNIDER ET AL., *supra* note 112.

117. OSCHNER HEALTH SYS., *Ochsner Clinic Foundation Research Informed Consent, in* IPACK NERVE BLOCK FOR TOTAL KNEE ARTHROPLASTY (2016), https://clinicaltrials.gov/ProvidedDocs/34/NCT03921034/ICF_000.pdf.

118. KAINOS MED., INC., *Consent to Participate in a Clinical Study, in* PHASE I, KM-819 IN HEALTHY SUBJECTS FOR PARKINSON'S DISEASE (2017), https://clinicaltrials.gov/ProvidedDocs/99/NCT03022799/ICF_001.pdf.

119. For an example of a consent form that had over 40% passive language but was otherwise fairly well written, see ELIZABETH R. SEAQUIST, CONSENT FORM: A RANDOMIZED DOUBLE BLINDED STUDY TO EXAMINE THE USE OF N-ACETYL CYSTEINE FOR THE PREVENTION AND TREATMENT OF HAAF IN PATIENTS WITH TYPE 1 DIABETES (2017), https://clinicaltrials.gov/ProvidedDocs/52/NCT02206152/ICF_001.pdf. Note that outside of the words, the lack of white space would make this difficult for anyone to read through.

uploaded consent forms that were templates—not completed consent forms. These templates typically presented numerous options to include depending on the study. Doing this, of course, adds to the word count of the form. Second, other studies uploaded multiple consent documents that were to be signed by the participants. For readability purposes, I scored these as a whole to get a sense of how all the forms scored for that study. However, because I did this, the word count for those forms were naturally higher. Despite this, there were a number of instances where a single consent form itself was over 10,000 words.[120] In the end, though, the median word length of 3,150 words seems more accurate based on my personal review of the forms. Many forms had a manageable length of under 10 pages with white space that made it look easy to navigate. Yet some others were dense pages of single-spaced text that ran on for 15–20 pages.

	FK Grade Level	Reading Ease	Word Count	Long Sentence %	Passive Sentence %
Average	9.37	51.7	3602.4	26.0	23.4
Median	9.40	52.0	3150.0	25.9	23.1

Table 3. Overall Averages & Median Scores for All Forms.

V. The 100 Best & Worst Scoring Consent Forms

Focusing on the best and worst consent forms can prove particularly enlightening, especially when looking for similar attributes on either end of the spectrum. To start, I separated out the top-100 and bottom-100 scoring forms based on their Flesch–Kincaid Grade-Level. Then I calculated the mean and median for each of the five metrics used to score all of the forms: Flesch–Kincaid Grade-Level, Flesch Reading Ease Score, consent word count, the percentage of long sentences, and the percentage of passive voice in the consent. After that, I used the study descriptions on ClinicalTrials.gov to further determine the types of studies that fell into the top and bottom 100.

A. Top & Bottom 100: Readability Results

The top-100 scoring forms had an average Flesch–Kincaid Grade Level of 7.8. This group had a median of 7.9. The Flesch Reading Ease average for the group was 59.2, with a median of 59. The best scoring form among the top 100 had a grade level of 5.4 and a reading-ease level of 70, and the bottom-scoring form among the

120. *See, e.g.*, LIB Therapeutics, LLC., Randomized, Double-Blind, Placebo-Controlled, Phase 2, Dose-Finding Study to Evaluate the Efficacy and Safety of LIB003 in Patients on Stable Lipid-Lowering Therapy Requiring Additional LDL-C Reduction (2018), https://clinicaltrials.gov/ProvidedDocs/60/NCT03549260/ICF_001.pdf.

top-100 forms had a grade level of 8.5 and a reading-ease level of 45. As stated earlier, only 52 of the 427 total forms scored below the 8.0 level, which means that nearly half (n=48) of the top-100 forms were in the 8.0–8.5 range. To be sure, many of these consent forms were still quite readable in this range—especially compared to some of the forms in the bottom 100.

For the bottom-100 scoring forms, the average grade level was an 11.0, with a median of 10.8. The Flesch Reading Ease average was 42.3, with a median of 45. The grade-level range for forms in the bottom 100 fell between 10.2 and 14.1 That means the best scoring form among the bottom-100 had a 10.2 grade level and the worst scoring form had a 14.1 grade level—that's a range between the sophomore-in-high-school level to the sophomore-in-college-level. The reading ease range for the best and worst in this group was a 52 for the best and a 29 for the worst scoring form.

What is really telling is the disparity among the averages in the two groups, at least based on these two readability measures. Comparing the best-of-the-best to the worst-of-the-worst is interesting, but it only looks at the difference between two extremes. The aggregate results from these two groups are more instructive. There was over a three grade-level difference (3.2 to be exact) between the average form in the top 100 and the average form in the bottom 100. To put this in more practical terms, the forms in the bottom 100 required that research participants read at three grade levels higher than those in the top 100. That's a heavy burden to place on participants in those studies. Moreover, as explained in more detail below, this disparity was not based on the difficulty of the studies in the bottom 100 versus those in the top.

B. Top & Bottom 100: Results for Other Metrics

As with the readability results, there was a wide disparity in the percentage of long sentences and passive voice in the top 100 versus the bottom 100. The content in the top-100 forms contained an average of 19.6% long sentences, with a median of 19.0%. The bottom-100 forms, on the other hand, averaged 32.4% of long sentences, with a median of 31.3%. For passive voice, the average percent of passive voice in the top 100 was 19.0%, with an 18.7% median. Those in the bottom 100 contained an average of 27.4% passive voice, with a median of 26.7% When comparing the two groups, this data helps to show why the forms in the bottom 100 may be considerably more difficult for the average U.S. adult to understand. On average, the consents in the bottom 100 contained 12.8% more long sentences and 8.4% passive voice than those in the top 100.

From a word-count perspective, the results seem inconsistent. The average word count of the top-100 forms was 3,809 words. The median word count was

3,597 words. However, the average word count for the bottom-100 forms was 3,126 words, with a median of 2,489 words. That means that the average harder-to-read form was 683 words shorter than the average easier-to-read form. Typically, you would expect that the top forms would be shorter than the bottom forms, since most people think that clarifying language means shortening it. Yet the number of words in a document is often counterintuitive. As most health-literacy and plain-language advocates know, creating understandable content often means adding more to it—more explanations, pictures, instructions, etc. The word-count metrics seem to support that view.[121]

Metric	Top-100 Average	Top-100 Median	Bottom-100 Average	Bottom-100 Median
Grade Level	7.8	7.9	11.0	10.8
Reading Ease	59.2	59.0	42.3	45.0
% Long	19.6	19.0	32.4	31.3
% Passive	19.0	18.7	27.4	26.7
Word Count	3809	3597	3126	2589

Table 4. Metrics for Top/Bottom 100.

C. Top & Bottom 100: Types of Studies in Each Group

After calculating the aggregate data for each group, I then explored the type of studies that fell within each group to see if certain types of studies were more likely to be among the top-scoring forms or the bottom-scoring forms. I calculated this data to help provide insight for a commonly stated reason for why consent forms are poorly written: many studies are high-risk and complex, so clearly explaining that complex study is difficult, if not impossible. So, I was interested to see if there were more behavioral studies in the top group that led to the better results since many of these are typically classified as low risk. To help determine this, using the researchers' own study description on ClinicalTrials.gov, I calculated the number of studies in the top-100 and bottom-100 that fell into one of the following categories:

(1) whether any phase number was listed for the study, which helped show it was intended to be a clinical trial,

121. Of course, increased word count is a matter of degree. If a form was increased from 3,800 words to 38,000 words, then even if it was easily understandable, the task would seem too daunting for most to even attempt. But if a 3,200-word document became a 4000-word document that had more white space, used easy-to-understand charts or graphics, and was written at a lower reading level, then this added length would not seem like a burden.

(2) whether it was listed as a phase 0, 1, or 2 study, which indicates that it might be higher risk given that it could be the first to test for safety or initial efficacy,[122]

(3) whether it was listed as a device study, which are given classification numbers based on the type of device,[123] not phase numbers, and

(4) whether it was labeled as a behavioral study, which might signify it was a low-risk study.

This did not account for all of the top-100 or bottom-100 studies though. There were some studies that were labeled differently—for example, diagnostic, procedural, or "other"—but the categories above still gave a good indication of the types of studies in each group.

For the top-100 studies, 49 were given a phase number, indicating they were clinical trials. Furthermore, 32 of these 49 were listed as a phase 0, 1, or 2 trial. Eleven were listed as device studies, while 22 were listed as behavioral studies.

For the bottom-100 studies, 31 were given a phase number, indicating that they were clinical trials. Of those 31 studies, 18 were listed as a phase 0, 1, or 2 trial. Sixteen were listed as device studies, while 20 were listed as behavioral studies.

Category of Study	Top-100 Group	Bottom-100 Group
Given a Phase	49	31
Phase 1 or 2	32	18
Device Study	11	16
Behavioral Study	22	20

Table 5. Count by Study Type in Top/Bottom 100.

Based on this data, it is evident that study type is not a valid reason for why some consent forms are more difficult to understand than others. In fact, the data show that the number of studies that might qualify as "difficult" or high risk was greater in the top 100 than the bottom 100. While there were five more device studies and two fewer behavioral studies in the bottom-100, there were 14 more

122. *See generally Phases of Clinical Trials*, NAT'L CANCER INST. (Feb. 6, 2020), https://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/phases (discussing the various phases of clinical trials).

123. *See generally Classify Your Medical Device*, FDA (Feb. 7, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

phase 0, 1, or 2 studies in top-100 group, which counters any notion that the bottom-100 may have contained more difficult studies that were harder to clarify. Instead, what this shows is that creating clear forms is a learned skill—it does not fully depend on the type of study. As will be further explained in the section below, there were plenty of studies that could be considered "easy" studies where the forms were exceedingly difficult to understand.[124]

VI. TEN TAKEAWAYS FROM THE TOP & BOTTOM 30

Since readability metrics do not necessarily mean that the form is understandable, I took a closer look at each of the top-30 and bottom-30 consent forms to better determine if the overall design, headings, and other features helped make the form easier or more difficult to understand. Overall, no consent was perfect. Some of the best-scoring forms overused bullet points, used ineffective designs, and used some medical and legal language that was not explained. But the top-30 forms were noticeably better than the bottom-30 forms. The bottom-30 forms often did multiple things to impede understanding, like overusing medical and legal terminology and cramming that terminology into long, passive, single-spaced paragraphs.

While reviewing each form individually, it became evident that there were patterns and practices that made a form more or less difficult to understand. The following are ten takeaways from this review, with quotes from some parts of the actual consents to help illustrate the concepts.

1. Takeaway: Use Question-Style Headings

One of the additional features I looked for in every consent from this group was the type of headings that were typically used. Vague, abstract headings can make it harder for a reader to determine just what that section is about. But question-style headings—those headings that pose questions the reader might ask themselves—are a widely accepted practice to help aid understanding.[125] For the top-30 forms, 66% (20 of 30) used question-style headings. However, in the bottom-30 forms, only 40% (12 of 30) used them. While the type of heading alone does not make a form difficult to understand, when coupled with long sentences, passive voice, and other medical or legal jargon, these features often create forms that seem impenetrable by those U.S. adults with average reading levels. Overall, though, I

124. For a straightforward study with a consent form that makes it seem overly complex, see JENNIFER LEVIN, IMPROVING MEDICATION ADHERENCE IN HYPERTENSIVE INDIVIDUALS WITH BIPOLAR DISORDER (2017), https://clinicaltrials.gov/ProvidedDocs/77/NCT02983877/ICF_001.pdf.

125. *See* Plain Language Action and Info. Network, *Add Useful Headings,* PLAINLANGUAGE.GOV, https://www.plainlanguage.gov/guidelines/organize/add-useful-headings/ (last visited Mar. 3, 2021).

was encouraged by the number of forms that used question-style headings—even those that otherwise scored poorly. These numbers tend to show that this practice is becoming a trusted method for creating documents that speak to the reader's anticipated questions.

2. Takeaway: Use Second-Person Language

I also looked to see how many of the top-30 and bottom-30 forms used second-person language instead of first-person or third-person language. Second-person language (e.g., you or your) makes consent forms seem like the researcher is speaking to the reader. Doing this helps make the reading experience more personal. It helps the "audience picture themselves in the text and relate to what you're saying. More than any other single technique, using 'you' pulls users into the information and makes it relevant to them."[126]

On the other hand, third-person language (e.g., he, she, the research subject) sets an abstract, disaffected tone that does not speak to the reader. That abstract tone is fine for research protocols, but not when directly addressing potential participants in a consent form. Third-person language also assumes that the reader knows that they fit within that third-person label—for example, that they are the "research subject" that is being referred to time and again in the consent.

As for first-person language (e.g., I, me, my), it may seem like a clear way to reference someone, and it does function that way at times. Yet, for consent forms, this first-person language can be counterproductive, making them read more like formal legal agreements. To be sure, first-person language can be helpful on the last page of the form, when seeking to affirm that the person has read the form or knows what they agreeing to. But using it when explaining the Common Rule requirements leads to abstract phrasing that can make things harder to understand. Notably, the two worst-scoring forms used first-person language, making them read more like legal agreements. For example, when explaining who qualifies to participate in the study near the top of the form, the worst scoring form stated the following:

> In order to participate in this study, I will need to have experienced at least one or more episodes of LBP in the past two weeks, I must be able to lie on my stomach for 30 minutes, and I must be able to tolerate OMT. I may not participate if I have had any prior spinal surgery, fractures, or known birth defects of the lumbar vertebra and sacrum. If pregnant (women only), I may be able to participant [sic], if I meet the above criteria. I cannot participate if I have a body mass index (BMI) over 28 kg/m^2 or have had any form of

126. Plain Language Action and Info. Network, *Address the User,* PLAINLANGUAGE.GOV, https://www.plainlanguage.gov/guidelines/audience/address-the-user/ (last visited Mar. 7, 2021).

> spinal manipulation, such as osteopathic or chiropractic manipulation, in the last 2 weeks. I should not participate nor be actively participating in any other medical research during the course of this study.[127]

Fortunately, though, nearly all the remaining consent forms used second-person language. All of the top-30 forms used it, as did 90% (27 of 30) of the bottom-30 forms. This is encouraging because such wide adoption of second-person language suggests that using it is now a standard practice in writing consent forms.

3. Takeaway: Explain Medical and Legal Terms You Must Use

When people think of plain language, they typically think of it as using simple words that people can understand. Of course, that is a part of the equation, but it oversimplifies what it means to create clear content that people can understand. It is best to think of it like this—avoid medical and legal terms you must use and explain those that you cannot avoid. In fact, past research suggests that people will prefer the added length if it helps explains complicated terminology.[128]

As you might expect, for this study, complex medical terminology and legal jargon were the norm. It was less prevalent in the top-scoring forms, but it was present in enough of them, nonetheless. It was even present in low-risk studies that should be easy to explain. For example, here is an overly legalistic paragraph from a study that only involved filling out surveys:

> If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: [address removed].[129]

Not surprisingly, the place where overuse of medical terminology was common was when describing what will happen during the study. Many of the bottom-scoring forms did not explain any medical terminology, while others explained

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127. SNIDER ET AL., *supra* note 112. This passage is bad on many levels, beyond just using first-person language. On a positive note, the form defined the terms LBP and OMT in the prior paragraph, not included here.

128. Christopher R. Trudeau & Christine Cawthorne, *The Public Speaks, Again: An International Study of Legal Communication*, 40 U. ARK. LITTLE ROCK L. REV. 249, 277–78 (2017).

129. URI LADABAUM, DOES KNOWING ONE'S ESTIMATED COLORECTAL CANCER RISK INFLUENCE SCREENING BEHAVIOR? (2018), https://clinicaltrials.gov/ProvidedDocs/20/NCT03819920/ICF_000.pdf.

them occasionally, yet not consistently. Here is an example where the term "withdrawn" was explained, but many were not:

> If you are undergoing an endoscopy scheduled by your doctor for your routine care, you will be asked to undergo an additional capsule balloon test before the endoscopy. If you agree, you will have screening without sedation using the capsule balloon test, just before your sedated upper endoscopy (EGD); the capsule balloon test is a new method that examines the esophagus without using sedative medications. . . .
>
> The balloon will be withdrawn until a tug is felt at the gastroesophageal junction (base of the chest) (GEJ). Once the GEJ is located, 10 cc of air will be removed and the 5 cc balloon will be pulled back 5 cm to sample the bottom of the esophagus. The balloon will then be completely deflated and then withdrawn (taken out) of your throat.[130]

4. Takeaway: Avoid Long Paragraphs and Those that Discuss Multiple Topics

Like long sentences, long paragraphs make it harder on readers. While the words of that paragraph could be clear and the sentences could be short, the long text walls "discourage users from even trying to understand your material."[131] While your paragraph length can and should vary, paragraphs should not be longer than 250 words, with most of your paragraphs under 150 words.[132] Also, "[t]here is nothing wrong with an occasional one-sentence paragraph."[133] Here is one extreme example of a long paragraph from one of the bottom-30 forms—this paragraph alone had a grade-level score of a 15.5:

> The risks and discomforts associated with your participation are related to the blood draws and possible side effects of the ivermectin. Ivermectin is generally considered to be very safe, but has not been extensively tested in pregnant women or immunosuppressed people. In clinical trials, the following clinical adverse reactions were reported as possibly, probably, or definitely related to the drug in 1-4% of the patients: nausea, diarrhea, changes in white blood cell count, abnormalities in liver function, swelling of the face, swelling of the arms/legs, blood pressure drop when standing

130. AMITABH CHAK ET AL., OFFICE BASED SCREENING TEST FOR BARRETT'S ESOPHAGUS (2016), https://clinicaltrials.gov/ProvidedDocs/24/NCT02451124/ICF_000.pdf.

131. Plain Language Action and Info. Network, *Write Short Paragraphs*, PLAINLANGUAGE.GOV, https://www.plainlanguage.gov/guidelines/concise/write-short-paragraphs/ (last visited Mar. 7, 2021).

132. *Id.*

133. *Id.*

> up quickly, fast heart rate and muscle pain. Drug-related headache occurred in <1% of patients (0.2%). If you are infected with a parasitic worm called *Loa loa* (the eyeworm) or *Onchocerca volvulus* (the parasite that causes river blindness), ivermectin may cause a severe reaction to dying worms. In order to avoid this, please do not take part in the study if you have travelled in the past 3 years to West or Central Africa (as this is the region of the world where it is possible to become infected with *Loa loa*) or other countries in which Onchocerciasis may be contracted. In addition, if you are currently taking Warfarin or have hepatitis you are not eligible to take part in the study. You will be required to stay at the CTRU for four hours after taking the dose of ivermectin in order for nursing staff to monitor you for any possible adverse effects, and will give prompt medical attention in case of any adverse effects. Risks associated with drawing blood include redness, swelling, pain or discomfort, and bruising at the site of the needle stick.[134]

The other problem with long paragraphs is that they frequently discuss multiple topics. The example above primarily discusses risks and discomforts, but it also includes study eligibility and exclusion, which someone might easily miss while slogging through that long paragraph.

Yet even short paragraphs can make understanding more difficult if the paragraph covers multiple topics. To be sure, there were many paragraphs, in both the top-30 and bottom-30, that frequently covered multiple consent requirements. For example, here is a short paragraph that covers no fewer than four Common Rule requirements—voluntariness, compensation, that there might not be a direct benefit to the participant, and lack of impact on medical care:

> Your participation in this study as well as any information communicated to HRA Pharma is entirely voluntary. You remain free to stop taking part in the study at any time if you wish to without affecting your care now or in the future. You will not be paid for taking part in this study. Also you will not benefit directly from this study, but it is hoped that your participation will help others in the future.[135]

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134. ADRIAN WOLSTENHOLME, UNIV. OF GA., *Consent Form: Ivermectin and Human Immunity*, in THE EFFECTS OF IVERMECTIN ON THE NORMAL HUMAN IMMUNE SYSTEM (2017), https://clinicaltrials.gov/ProvidedDocs/94/NCT03459794/Prot_SAP_ICF_000.pdf. Unlike most other consent forms, this consent form was included in the PDF with the study protocol, so I extracted it before scoring just the consent form.

135. PAUL FINE ET AL., PROSPECTIVE OBSERVATIONAL STUDY TO ASSESS CLINICAL FOLLOW-UP AND OUTCOMES OF PREGNANCIES EXPOSED TO ELLA® (ELLIPSE II), at 30 (2015), https://ClinicalTrials.gov/ProvidedDocs/37/NCT01569737/Prot_ICF_001.pdf.

5. Takeaway: Avoid an Overly Formal Tone

The tone of a document is a key factor that many overlook. Tone can make the document seem formal or informal. In theory, a document can be too informal, but though people often suggest this as a criticism of plain language, I have yet to see an IRB-approved document that is too informal. On the other hand, many consent forms adopt a far-too-formal tone. Many times, that formal tone is coupled with medical and legal jargon that also make it hard to decipher. Here is an example from a consent form that had a decent layout and used informative headings, yet adopted an overly formal tone and failed to explain medical terms:

> If you decide to participate, you will be escorted by the research coordinator to a dressing room, where you will change into a gown. Then, you will receive acoustic angiography ultrasound exam in conjunction with the standard diagnostic imaging, including b-mode ultrasound. We may also do another FDA approved ultrasound with the acoustic angiography imaging. Acoustic angiography imaging will be performed by a trained medical personnel using mild compression to eliminate motion, similar to when you received your breast ultrasound. The total imaging time is estimated to be less than 15 minutes.[136]

The other problem with an overly formal tone is that it signals to readers that this document is going to be a chore to read through. Those forms that start off with a formal tone are more likely to lose readers than those that draw readers in with language they can relate to. One consent form from the bottom-30 started off with this:

> Prior to give [sic] your consent to study participation, it is important for you to read and understand the information given in this document. It describes the purpose, procedures, advantages, potential risks and inconveniences related to this study, as well as your obligations as a study participant. It also describes alternative procedures available for you and your rights for study participation discontinuation at any time. No warranties and statements are made with regard to the study results. After you familiarize yourself with this document and receive all answers to the

136. YUEH LEE ET AL., COMPARISON OF THE SPECIFICITY OF ACOUSTIC ANGIOGRAPHY (MICRO-TUMOR DETECTION BY QUANTIFYING TUMOR-INDUCED VASCULAR ABNORMALITIES) TO THE SPECIFICITY OF CONVENTIONAL ULTRASOUND (2018), https://ClinicalTrials.gov/ProvidedDocs/28/NCT02175628/ICF_001.pdf.

> questions you are interested in, you will be offered to sign the Consent Form.[137]

If the consent starts out like that, imagine reading the rest of the over 2,900 words of this consent form—it had a 12.5 grade level, used long sentences 29.19% of the time, and used the passive voice 27.75% of the time.

6. Takeaway: Avoid Nominalizations that Lead to Passive Sentences

As discussed earlier, overusing the passive voice can make it harder to determine who is doing the action—or who is supposed to do what.[138] What makes this worse is when the writer also uses nominalizations, instead of base verbs to describe the action.[139] Nominalizations occur when a writer turns an action verb into a noun, and uses that instead. Typically, words that end in -tion, -ment, -ance, and similar variants signify a possible nominalization.[140] For example, "to pay" is an action verb but "to issue payment" is turning "pay" into a nominalization. Not all nominalizations are wrong or avoidable, but they typically require helping words that make the sentence longer and they obscure the action by making it more abstract. Also, while an active sentence can include nominalizations, they tend to be more prevalent in passive sentences, which further adds to the difficulty of those sentences.

For this study, many forms—from both the top and bottom 30—used some passive sentences that included nominalizations. But the practice was far more pronounced in the bottom 30. Here is one example from a consent form that could be improved by using action verbs instead of nominalizations:

> You understand that your participation in this study may not benefit you directly. Possible benefits of your participation in the research study are the expectation that society may benefit from a significant contribution to medical knowledge. This knowledge of conditions, types of injuries, surgeries, complications and results may provide surgeons with research information that will help to establish a better understanding of the

137. OMNIFARMA KIEV, LLC ET AL., RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTI-CENTER STUDY OF EFFICACY OF THE ADMINISTRATION OF COLLOIDAL SILICON DIOXIDE IN TABLET DOSAGE FORM (CARBOWHITE) IN PATIENTS WITH ACUTE DIARRHEA 31 (2015), https://clinicaltrials.gov/ProvidedDocs/44/NCT03633344/Prot_SAP_ICF_000.pdf.

138. *See* ADAMS, *supra* note 97, at 48.

139. RICHARD C. WYDICK, PLAIN ENGLISH FOR LAWYERS 23 (5th ed. 2005).

140. *Id.* at 24.

> management and treatment of orthopaedic patients and will especially prove to be valuable as our population ages.[141]

In this example, using words like participate, contribute, expect, and manage instead of their nominalization counterparts would force the writer to make this passage active. This would help make it clearer and more direct.

7. Takeaway: Use References to Everyday Life to Help Explain Concepts

One of the most difficult things about clearly explaining research-related rights and concepts is explaining concepts that many are not familiar with. One way to handle this is to explain how those concepts relate to everyday occurrences in people's lives. For example, data protection and security are difficult concepts for people to understand, but one of the ways to explain those is to liken it to how others protect information, like credit card companies. One consent form did this well with the following language:

> Our research team will keep your personal information private and encrypted. This research is being run from a 'secure' server like the kind many companies use for credit card transactions. It will only be used for the research project and only the research team will have access to your information.[142]

In addition to this, the overall consent form was also well written—the grade-level score for the entire consent was a 6.7.

8. Takeaway: Limit Your Lists to Related Material

Breaking up complicated material into lists is a commonly known best practice for making material easier to understand. It works particularly well for explaining a series of requirements to qualify for something or to explain steps in a process.[143] Because of this, lists work well in consents where both explaining processes and requirements are the norm.

But the problem with lists is when they are not targeted to one topic. That is, the writer throws out a litany of bullet points of related content, tangentially related

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141. KEVIN M. MARBERRY, EFFECTS OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) ON POSTOPERATIVE PAIN AND FUNCTION FOLLOWING ARTHROSCOPIC KNEE SURGERY: A PROSPECTIVE RANDOMIZED CLINICAL TRIAL PILOT STUDY (2011), https://ClinicalTrials.gov/ProvidedDocs/28/NCT01528228/ICF_001.pdf.

142. PATIENT WELL-BEING RESEARCH PROJECT: PARTICIPANT INFORMED CONSENT FORM (2017), https://clinicaltrials.gov/ProvidedDocs/13/NCT03060213/ICF_001.pdf.

143. *See* Plain Language Action and Information Network, *Use Lists*, PLAINLANGUAGE.GOV, https://www.plainlanguage.gov/guidelines/organize/use-lists/.

content, and unrelated content and expects the reader to do the work of sorting them out. I call this the shotgun approach to bulleted lists. This happens a lot in all sorts of documents. While this can help lower the readability level of a form, since each list item is seen as a separate sentence, it does nothing to help show relationship among items in the list. Here is a good example of a targeted list from a consent form that had an overall grade level of 7.2:

> You do not have to take part in this study to receive treatment for your chronic plantar fasciitis. If you decide not to take part in this study, other alternatives include:
>
> - Standard of care treatments (orthotics and immobilization boot)
> - rest, stretching and strength training
> - OTC painkillers
> - Steroid shots
>
> Your study doctor will discuss these options, and their risks and benefits, with you.[144]

9. Takeaway: Do Not Hide Information that Matters to Participants

In journalism, they call it "burying the lede."[145] This occurs "when the important elements of a story are tucked down into the details, obscured by less important, distracting information . . . ."[146] This, of course, is not a good practice in any type of writing, but for consent writing, it takes on greater significance. After all, volunteers are agreeing to subject themselves, and often their bodies, to numerous activities to help advance science. Yet, we know that, too often, people are not aware of what they are agreeing to endure.

Outside of what else has been discussed above, one of the things that exacerbates this problem is when researchers obscure things that are important to participants by putting them in the middle of paragraphs, after first explaining things that are less important to the participant. For example, the following excerpt buries a key activity that would be vital for most to know before agreeing to be in the study:

> You will be randomly assigned to the trials (1) - (3) after (0) is complete. Treatment order will be counterbalanced amongst the participants. Testing sessions will occur with a minimum of one day between testing. This will

144. Bob Baravarian, INFOMED CONSENT FORM AND HIPAA AUTHORIZATION: PRELIMINARY PROTOCOL FOR INTENSE THERAPEUTIC ULTRASOUND FOR THE TREATMENT OF CHRONIC PLANTAR FASCIITIS (2016), https://clinicaltrials.gov/ProvidedDocs/02/NCT03254602/ICF_000.pdf.

145. *Why Do We 'Bury the Lede?'*, MERRIAM-WEBSTER USAGE NOTES, https://www.merriam-webster.com/words-at-play/bury-the-lede-versus-lead (last visited Mar. 11, 2021).

146. *Id.*

> allow for adequate recovery of the participant and allow you to return to baseline after exercise in the heat. . . .
>
> Upon arrival to the laboratory, your nude body mass, body fat percentage using Jackson & Pollack's 3- site skin fold measurement, height, urine color, and urine specific gravity will be measured. You will be instructed on the use of the investigational Thermal Rehab Machine (Polar Breeze, Statim Technologies), and self-administration of rectal thermometer. The rectal thermometer is a small (4mm [0.15 inch diameter) flexible probe. You will also be familiarized with three perceptual measures: Environmental Symptoms Questionnaire (ESQ), Rating of Perceived Exertion (RPE) and Thermal sensation scale. Lastly, the familiarization session will also involve an assessment of the your [sic] cardiovascular fitness, which will be used to determine the exercise intensities during each exercise session.[147]

Did you catch that? In order to be in the study, you have to check your own rectal temperature. Additionally, the consent phrases this in the abstract—"self-administration of a rectal thermometer"[148]—which further obscures the message. In either case, doing this task would be a major impediment to joining the study for many people, and it is certainly more important to know than what the passage starts off with randomization of the differing control groups. The good news is that this problem can be easily avoided by organizing information according to what matters to the study population instead of what matters to study reviewers, potential funders, or the researchers themselves.

10. Takeaway: Do Not Copy and Paste from the Protocol

Relatedly, one of the common trends in the bottom-30 forms was language that seemed to be taken directly from the study protocol. This typically occurred in the study explanation section of the consent forms. For example, here is one example that reads like it was taken directly from the study protocol:

> The primary aim of the study is to ascertain the physical activity patterns in those with pulmonary sarcoidosis with regards to perceived physical activity and actual physical activity. The secondary aim of the study is to understand the effect of pulmonary sarcoidosis in relation to muscle strength and exercise capacity against physical activity, lung function and

147. WILLIAM M. ADAMS, UNIV. N.C. GREENSBORO, *Consent to Act as a Human Participant, in* EFFICACY OF AN INVESTIGATIONAL THERMAL REHAB MACHINE ON BODY COOLING IN HYPERTHERMIC INDIVIDUALS 2 (2018), https://ClinicalTrials.gov/ProvidedDocs/35/NCT03643835/ICF_000.pdf.

148. *Id.*

> oxygen saturation and how these differ from normative values. Unfortunately, Sarcoidosis has a chronic shortage of research. This lack of research is coupled with current researchers' focus solely on results of tests such as lung function, at the expense of patient feedback on the condition, despite lung function being shown to be a poor indicator of overall health, including primary and secondary symptoms within Sarcoidosis, and current treatment methods (corticosteroids) causing several detrimental side effects. Therefore, the purpose for the current study and its future applications are to better understand physical activity and other measurements such as muscle strength as indicators of health within Sarcoidosis as well as identifying possible areas for future study in relation to non-pharmacological treatments.[149]

Researchers and funders talk about study aims; participants care about what might come out of the study—a vaccine, a new device, more knowledge on a particular method, etc. These may technically mean the same thing, but that meaning is lost on those who do not have the knowledge that researchers have. Notably, this passage was presented exactly like this in the consent form—it was one long, single-spaced paragraph.

Of course, the real problem with taking material from the study protocol is that the intended audiences are different. Research participants are not trained study reviewers, sponsors, or compliance professionals. They are not used to reading information like this, and they will typically lack the knowledge to understand it. What's more, since research participants are essential to conducting human-subjects research, they deserve information that was crafted especially for them.

VII. CONCLUSION

As a whole, this study helps to provide the baseline data needed to measure whether the changes in the Revised Common Rule have had any impact on how consent forms are written. Overall, from a readability standpoint, it is clear that the average U.S. adult will struggle to read the vast majority of consent forms posted on ClinicalTrials.gov before the Revised Common Rule took effect.[150] Specifically, 60% of the consent forms had a readability level above the 9.0 grade level, and only 12% of the forms scored at or below the recommended 8.0 grade level.

149. KINGSTON UNIV. LONDON, INFORMATION SHEET: THE ROLE OF PHYSICAL ACTIVITY AND DIET WITHIN PULMONARY SARCOIDOSIS (2017), https://clinicaltrials.gov/ProvidedDocs/36/NCT03336736/ICF_003.pdf.

150. *See* Eltorai et al., *supra* note 1, at 1181.

To be sure, there are limitations to this data. As explained earlier, the fact that the documents uploaded to ClinicalTrials.gov were not required to be submitted before 2017 creates some selective deposit bias. Additionally, the PDF nature of the uploaded documents to ClinicalTrials.gov hindered the ability to "prepare" the document before measuring them with VT Writer. Because of this, the readability results from this study would, actually, be slightly worse than the unprepared data that this study suggests. Despite this, the results show that there is work to do to make consent forms more understandable to the general public.

Relatedly, perfection or complete understandability should not be the goal of these written forms. There will also be people on the extremes that need or want something different. Importantly, informed consent is a process that involves both written documents and verbal discussions with the research team. It is that combination that can help reach every person in the study population. Because of this, the goal for these written consents should be to consistently produce clear, readable consents that the average U.S. adult can understand.

Perhaps the most important thing that this study helps to show is that, across the board, it is an active choice to write in an understandable way. It is a trainable skill. Both the best forms and the worst forms dealt with difficult subject matter, yet the best forms consistently explained things in a more understandable way, using some or all of the takeaways explained above. Researchers can no longer hide behind this shield of alleged study difficulty. Because writing clearly is a trainable skill, it raises ethical questions about those researchers who do not take the time to create a consent form that is understandable to their study population. Moreover, since the Revised Common Rule has now mandated that researchers create consents that are understandable to the research participant, these pre-Revised Common Rule results set the baseline for determining whether these new requirements are producing that desired result.