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Perspectives of IRB Chairs on the Informed Consent Process

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Abstract

Background: Questions have been raised by researchers and ethics committees about whether human research subjects comprehend study participation when signing a research consent form.

Methods: To determine existing beliefs about the informed consent review process, impediments to shorter consent, and augmented/alternative consent methods, a survey of Institutional Review Board (IRB) chairpersons was conducted.

Results: IRB Chairs expressed concern with (but do not often assess) the length, complexity, and reading level of the consent form or participant comprehension. IRB chairs reported varied (but generally low) familiarity, acceptance, and use of possible solutions and alternatives.

Conclusions: Best practice standards should be developed for (1) assessing consent form reading level; (2) measuring and monitoring participant comprehension; (3) alternative consent methods and enhancements; and (4) electronic signatures.

Keywords

Informed Consent; Electronic Consent; IRB; Consent Comprehension; Participant Comprehension; Multimedia Consent; Enhanced Consent; Consent Reading Level

Introduction

In a digital age, the standard of practice for research informed consent remains largely a signed paper consent form. Federal regulations are clear about the need for documentation of informed consent and the elements required to be disclosed when attempting to obtain informed consent (DHHS n.d.). Common regulatory interpretation calls for an Institutional Review Board (IRB) to review and approve a consent form to document consent with the subject's signature. The problems posed by the consent process are due to consent

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documents being perceived as the primary method to secure informed consent rather than the conversation between the participant and the investigator (May, Craig and Spellecy 2007). Lengthy, detailed paper consent forms overload potential participants with information and may lead subjects to dismiss the risks thereby compromising the informed consent process (May et al. 2007).

Compromised informed consent has been observed in up to 70% of research since participants are confused about at least one required element of informed consent (Mason and Allmark 2000). Participant comprehension of the critical aspects of the study diminish over time with no association to age, gender, monthly family income, neighborhood, or level of education (Mexas et al. 2014). Participants sometimes sign the consent document without understanding what participation entails (Rowbotham et al. 2013). At the same time, investigators point out that IRB reviews sometimes ask that even more information be provided on a consent form, require changes for stylistic purposes, and require changes that do not concern safety or benefits but emphasize study design (Spellecy and May 2012). The exclusive focus on the informed consent document by IRBs undermines the premise that informed consent is a process rather than a checkbox (Emanuel et al. 2004). Further, it raises questions about whether IRBs have been able to keep pace with research participants who live in an increasingly digital world.

Nevertheless, evidence-based methods to improve informed consent comprehension are available, including: enhanced consent (Ballard et al. 2011; Sato et al. 2014), teach-back/read-back (Fink et al. 2010; Prochazka et al. 2014; Tamariz et al. 2013; White et al. 1995), multimedia modules to enhance the current process (Batuyong, Birks and Beischer 2012; Beamond et al. 2009; Migden, Chavez-Frazier and Nguyen 2008; Rowbotham et al. 2013), multimedia modules to replace the current process (Cornoiu et al. 2011; Sonne et al. 2013), participant information leaflets/booklets (Armstrong et al. 2012; Coletti et al. 2003), and study map/decision aids (Bhutta 2004; Foradori and Nolan 2012; Juraskova et al. 2007). Even though some of the above studies focused on clinical rather than research consent, the same alternative consent models might help to change the way researchers talk with potential research participants.

A review of 54 interventions to improve informed consent in patients and/or research participants found that 50% of extended discussion interventions, 41% of enhanced consent form interventions, 33% of test/feedback interventions, and 31% of multimedia interventions showed significant improvement in understanding of study benefits and risks by subjects (Nishimura et al. 2013). Importantly, the authors reported that none of the research informed consent interventions studied had a negative impact on participant satisfaction or study accrual (Nishimura et al. 2013).

Despite the evidence that enhanced informed consent methods, including digital media, may be at least as effective as the current process in assuring participant comprehension, IRB perspectives on the current use of such methods are not known. Because the IRB is empowered with decisional authority over the informed consent process by DHHS regulations, IRB views on consent comprehension, and willingness to approve enhanced consent models, are critical to the use of such methods in practice (DHHS 1979 (amend.

2009 Jan 15)). Comprehension of the study is a critical component of an individual's ability to provide informed consent to participate in research, yet it is unclear whether participant comprehension is widely assessed by IRBs. To address this knowledge deficit, an anonymous key stakeholder survey of IRB chairs was conducted. Because no information or standards exist for IRBs considering these methods, we hypothesized that the IRBs would have varying levels of experience and acceptance of such methods.

Methods

Study sample

We identified 350 IRB chairperson email addresses through an extensive internet search. The IRB chairs were first sent an introductory email explaining the nature of the forthcoming anonymous online survey. Two days later, the online survey was sent to IRB chairs who had not declined participation.

Survey instrument

Survey questions were developed from a literature review gap analysis. The survey was modified to its current form after pilot testing and comments from two IRB administrators. IRB chairpersons were surveyed regarding beliefs about the informed consent review process, augmented or alternative consent methods, and current practices. Survey questions incorporated three content domains: (1) background information about the respondent's IRB, (2) practices and concerns regarding informed consent, and (3) a case scenario with web-based informed consent to assess whether the IRB would approve such a method (Appendix 1). For selected questions, we provided space for free text for respondents to make open-ended comments. The 19-question survey required approximately 10 minutes to complete and was conducted through SurveyMonkey.com. Study procedures were reviewed by the Johns Hopkins Bloomberg School of Public Health and deemed to be a key informant survey and not human subjects research as defined by DHHS regulations 45 CFR 46.102.

Results

Sample characteristics

Key characteristics of the IRBs surveyed and activities reported by IRB chairs are displayed in Table 1. In all, 114 of 350 IRB chairs completed a questionnaire (33% response rate). Respondents were primarily chairpersons of university IRBs and academic medical center IRBs. Most of the research reviewed by these IRBs was biomedical rather than social or behavioral. More than half reported having large numbers of studies under IRB review (> 500 studies). 61% of IRB chairs reported that the average length of the informed consent document for studies reviewed by their IRB was 10 to 20 pages. Most IRBs do not assess reading level of documents and do not assess comprehension of consent.

IRB practices

The majority of IRB chairs (68%) noted that their IRB has frequently discussed concerns about the level of participant comprehension. However, according to the IRB chairs who responded to the survey, 38% reported that their IRB never monitors study participants'

informed consent comprehension, 39% reported rarely monitoring, and 19% reported monitoring less than half of studies.

Situations encountered in reviews

Table 2 provides the frequency of issues IRBs encounter during review of consent documents provided by investigators proposing to conduct human subjects research. In more than half of reviews, the IRB chairs noted that the IRB's focus is largely on written documentation of informed consent rather than the comprehension of the study participants. The consent document was felt to be lengthy and complex, and higher than an 8th grade reading level.

Alternative methods of obtaining and documenting consent are rarely proposed. Fully 98% of IRB chairs reported rarely or never encountering a proposal for the use of multimedia consent modules instead of a paper form, and 88% of IRB chairs reported rarely or never encountering a proposal for the use of electronic signatures for informed consent.

When asked which enhancements to the informed consent process have been observed by their IRB, 70% of respondents reported using participant information leaflets, 44% reported using teach-back/read-back techniques, 39% reported using post-consent comprehension assessment questionnaires, 30% reported using study maps (visual maps depicting the flow of participants through the course of a study), 18% reported using multimedia education modules, 19% reported using decision aids, and 6% of respondents reported recording the informed consent discussion. Some respondents commented that these methods are seen in proposals but rarely are they required by the IRB.

Web-based consent process scenario

The IRB chairs were asked to read the case scenario in Appendix 1 and answer a series of questions about the acceptability of the procedures proposed. For 43% of the respondents, a multimedia consent module method as described in the scenario would likely not be approved by their IRB as a stand-alone consent process, but might be approved as an enhancement to the traditional informed consent process. Forty percent thought the multimedia consent procedure would be approved. In 6% of cases, IRB chairs thought a multimedia method of consent would not be approved, and in 10% of cases, IRB chairs were uncertain that multimedia consent would be acceptable.

Sixty-five percent of respondents noted that that their IRB does not currently use documentation of informed consent by electronic signature (e.g. with stylus and electronic signature pad or an iPad); however, 63% affirmed that the method would be approved by the IRB. Of the respondents who were unsure whether their IRB would approve the use of an electronic signature, some stated that their IRB had never considered electronic documentation of consent and were unsure of the legal validity and what information technology standards and statutes (i.e. HIPAA) would apply. One respondent noted that, although they would support this method, acceptability for FDA-regulated studies was unclear.

When asked what additional information would be requested by their IRB when considering an electronic informed consent procedure, respondents stated that their IRB would consider these methods in the context of the risk-benefit ratio for each study. Some stated that electronic signatures would only be considered for minimal risk studies. Respondents expressed uncertainty regarding the FDA acceptability, legal validity, requirements of state/local law, and storage/documentation of electronic signatures. For multimedia modules, respondents questioned the ability of investigators to present the information in hard copy if requested by the participant or IRB.

Discussion

The results of this survey indicate that many IRBs have yet to consider emerging methods to enhance or supplement the informed consent process. The IRB chairs expressed varying (but low) degrees of familiarity with concepts like multimedia consent modules and electronic signatures for documentation of consent. The majority of chairs responded favorably to the use of electronic signatures for documentation of consent provided that it was in compliance with state and federal laws and regulations. Their opinions of multimedia consent modules were also favorable, though the chairs were split on whether modules could replace the consent *form* or endorsed only as an enhancement to the existing process. Information on how IRB Chairs perceive the use of newer methods to ensure informed consent, including electronic signatures, is all the more timely since the FDA has recently released draft guidance supporting the use of electronic informed consent (FDA 2015).

Before discussing the implications of our findings, we must address study limitations. First, we had few responses from independent (i.e., corporate) and government-operated IRBs. Due to low response rates from chairs of these IRBs, the viewpoints and unique challenges faced by independent IRBs are not well represented in the results. If the IRB Chairs who were most interested in the informed consent process responded to the survey, then our estimates of IRBs that, for example, check the literacy level of documents, may be conservative. Second, the potential for impact of reliance on a non-local IRB (i.e., a single IRB of record for a multi-site study) on the alternatives examined in this survey was not investigated. Third, while the results of this study identify the perspectives of IRB chairs on various consent issues, we did not explore the rationales behind these perspectives. Without knowing what perspectives IRB chairs would hold prior to this study, we could not design structured follow-up questions a priori on beliefs that had not yet been established.

Despite limitations, our findings are noteworthy because new methods are emerging to obtain informed consent and to make informed consent more interactive and tailored to the potential participant. The IRBs represented by the chairpersons who responded to this survey comprise a wide range of domestic institutions. The IRBs were largely focused on biomedical research rather than social and behavioral research. Given that the call for IRBs dedicated to social and behavioral research is a relatively recent development in the history of human research protections (De Vries, DeBruin and Goodgame 2004), the large proportion of biomedical IRBs was not surprising. The majority of respondents represented IRBs associated with academic institutions or hospitals, which also reflects the general population of IRBs. The majority of IRBs were accredited by the Association for the

Accreditation of Human Research Protection Programs, a rigorous certification process requiring well defined policies and procedures for IRB operations.

According to our findings, IRB Chairs are concerned about whether research participants comprehend the information they receive during the informed consent process. But the rate of informed consent comprehension monitoring reported by our respondents was low (77% reported either never or rarely monitoring comprehension). Among institutions that are monitoring consent comprehension, a variety of methods were identified, suggesting a lack of guidance or a solid evidence base for a best practice. In institutions where the IRB does not monitor informed consent comprehension, some IRB Chairs stated a belief that comprehension assessment was exclusively the responsibility of the researcher and not the IRB. While it is true that the research investigator has an obligation to ensure that a participant understands what participation entails (OHRP 2016), the IRB is granted the authority “to observe or have a third party observe the consent process and the research” (DHHS 1979 (amend. 2009 Jan 15)). The belief that the responsibility rests solely with the research investigators may contribute to the disconnect between IRB perspective and practice and could offer an opportunity for improvement. Numerous respondents stated that their IRBs have not approved various alternative consent or comprehension assessment models only because the research investigators have not yet proposed such uses at their respective institutions at this time.

Notable concerns about the effectiveness of the existing informed consent process were the length, complexity, and reading level of the consent form and the focus of both the IRB review and the consent form on written documentation and not ensuring participant understanding. According to the respondents, the average length of informed consent documents reviewed by their IRB ranged from less than 10 pages to more than 25 pages (though most respondents noted an average length between 10 and 20 pages). This variation may be a result of institutional boilerplate language or might be characteristic of the differing requirements and preferences of each local IRB. On the other hand, IRB chairs disagreed with the notion that long and complex consent documents are due to frequently identified issues such as excessive risk sections or legal boilerplate from institutions and sponsors (Table 2). Further research should examine what other issues could be the cause of this problem.

Conventional wisdom states that consent forms should be written in plain language at no greater than an 8th grade reading level (NHLBI 2011). In all, 70% of respondents noted that their IRB does not assess the reading level of consent forms. Despite the self-identified lack of regular reading level assessment, IRB chairs also reported that consent documents reviewed by their IRBs appear to be consistently written in language higher than the 8th grade reading level. The disconnect between best practices and reality likely results in comprehension difficulties for potential research participants.

Before calling on IRBs to develop or enhance consent comprehension monitoring programs, it is important to note the existing workload of the IRBs and human research protection offices. Over half of the IRBs surveyed have a portfolio of more than 1,000 active human research studies and review more than 20 new studies each month. Asking IRBs to adopt a

systematic assessment of informed consent comprehension may require additional resources or re-direction of existing resources.

Official guidance and best practice standards should be developed for (1) assessing consent form reading levels; (2) measuring and monitoring participant comprehension of the informed consent process; (3) alternative consent methods and enhancements; and (4) electronic signatures for documentation of informed consent. Guidance from the Office of Human Research Protection (OHRP) and the U.S. Food and Drug Administration (FDA) and best practices established by the Association for the Accreditation of Human Research Protection Programs should be informed by empirical research on factors and processes involved in the informed consent process and participation comprehension.

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Appendix 1

Survey of IRB Chairpersons

Part 1 - Background Information

1. How would you describe the primary role of your IRB? (Please select one)
 - a. Medical/Public Health School IRB
 - b. University IRB
 - c. Hospital IRB
 - d. Independent IRB
 - e. Government IRB
2. What is the primary focus of your IRB? (Please select one)
 - a. Biomedical Research
 - b. Social and Behavioral Research
3. Is your IRB accredited through the Association for the Accreditation of Human Research Protection Programs (AAHRPP)? (select one)
 - a. No, my IRB is not accredited.
 - b. No, but my IRB is currently applying for accreditation.
 - c. Yes, my IRB is accredited.
4. How many active studies (new and continuing) are currently being reviewed by your IRB? (Please select one)
 - a. Less than 100 studies
 - b. 100–250 studies

- c.** 251–500 studies
- d.** 501–1000 studies
- e.** More than 1000 studies
- 5.** How many new research studies are reviewed by your IRB per month?
(Please select one)
- a.** Less than 5 studies
- b.** 5–10 studies
- c.** 11–15 studies
- d.** 16–20 studies
- e.** More than 20 studies
- 6.** How long is the average informed consent document approved by your IRB?
(Please select one)
- a.** Less than 10 pages
- b.** 10–15 pages
- c.** 16–20 pages
- d.** 21–25 pages
- e.** Greater than 25 pages
- 7.** Does your IRB assess the reading level of your informed consent documents using a validated instrument (e.g. Flesch-Kinkaid)? (Please select one)
- a.** No, reading level assessment with a validated tool is not required.
- b.** Yes, but less than half of studies are assessed.
- c.** Yes, and more than half of studies are assessed.
- d.** Yes, reading level assessment with a validated tool is required for all studies.
- 8.** Does your IRB currently allow documentation of informed consent by electronic signature (e.g. with stylus and electronic signature pad or an iPad)? (Please select one)
- a.** Yes
- b.** No
- Part 2 - Consent Comprehension and Concerns
- 9.** Has your IRB raised concerns regarding the level of participant comprehension of the informed consent process for research studies? (Please select one)
- a.** No, our IRB has no concerns regarding the level of participant comprehension.

- b. Yes, our IRB has rarely discussed concerns regarding the level of participant comprehension.
 - c. Yes, our IRB has occasionally discussed concerns regarding the level of participant comprehension.
 - d. Yes, our IRB has frequently discussed concerns regarding the level of participant comprehension.
10. Does your IRB monitor study participants' informed consent comprehension?
- a. Never
 - b. Rarely
 - c. Less than half of studies
 - d. More than half of studies
 - e. Almost every application
11. How does your IRB monitor study participants' informed consent comprehension? (select all that apply)
- a. Direct observation of the informed consent process by third-party informed consent monitors.
 - b. Participants are asked to "teach-back" key aspects of the study prior to enrollment.
 - c. Participants are asked to take a study-specific comprehension assessment prior to enrollment.
 - d. Other. Please explain in a generalized manner so as to maintain anonymity: [OPEN TEXT FIELD]
 - e. Comprehension is not monitored by the IRB.
12. Please rate how frequently the following issues are encountered by your IRB during the review of proposed human subjects research?

	Never	Rarely	Less than half of studies	More than half of studies	Almost every application
The focus is largely on written documentation rather than on ensuring that potential participants understand the entire research process.					
The written documentation process and the language used are based on a desire to provide legal protection to researchers and sponsors of the research rather than to provide information to participants.					

The information provided under various items in the informed consent process, such as sponsorships, funding, assured benefits, and risks, is excessive.					
The consent document is lengthy and complex.					
The consent document is higher than an 8th grade comprehension/reading level.					
IRB Members disagree on the best means of providing information to ensure that the potential participants truly understand the nature of the research and the possible risks and benefits.					
Alternative methods of obtaining consent, such as recorded or witnessed consent using third parties or community representatives, are used.					

13. Which of the following informed consent enhancements does your IRB currently utilize? (select all that apply)

- a. Post-consent questionnaires to assess understanding
- b. Teach-back/Read-back
- c. Multimedia education module
- d. Decision aids
- e. Study maps
- f. Participant information leaflets
- g. Informed consent discussion recording
- h. Other. Please explain in a generalized manner so as to maintain anonymity: [OPEN TEXT FIELD]

14. If not currently being used, which items from the previous question has your IRB considered implementing in the future? (select all that apply)

- a. Post-consent questionnaires to assess understanding
- b. Post-consent teach back/read back
- c. Multimedia education module
- d. Decision aides
- e. Study maps
- f. Participant information leaflets
- g. Informed consent discussion recording
- h. Other. Please explain in a generalized manner so as to maintain anonymity: [OPEN TEXT FIELD]

Part 3 - Case Scenario

An investigator has asked the IRB for permission to use a new informed consent method. The investigator proposes creating video presentations with pre-recorded multimedia modules explaining the nature of a research study and the associated risks and potential benefits of participation. These modules would be reviewed in advance by the IRB. The investigator plans to have potential participants proceed through the prepared modules on a computer, and then be able to ask a research team member questions about the study. Participants who want to join the study would then take a brief quiz to assess comprehension. If the potential participant answers all questions correctly, signing an electronic signature pad with a stylus documents the informed consent.

15. If the multimedia consent modules include all of the required elements of informed consent from the Common Rule, would your IRB approve this proposed consent procedure? (Please select one)
 1. This method would likely be approved by our IRB.
 2. This method would likely not be approved by our IRB as a stand-alone consent process, but would be approved for use as an enhancement to the traditional informed consent discussion between the investigator and the potential participant.
 3. This method would not be approved by our IRB because the multimedia module does not include institution-specific boilerplate information.
 4. This method would not be approved by our IRB because: [OPEN TEXT FIELD] (Please respond in generalizations so as to maintain anonymity).
16. Would your IRB approve the use of an electronic signature pad and stylus for documentation of informed consent?
 1. This method would be approved by our IRB.
 2. This method would not be approved by our IRB because our IRB requires signature on a paper form for documentation.
 3. This method would not be approved by our IRB because:
[OPEN TEXT FIELD] (Please respond in a generalized manner so as to maintain anonymity).
17. What additional information would your IRB require for review?
[OPEN TEXT FIELD] (Please respond in a generalized manner so as to maintain anonymity).
18. Has your IRB previously encountered the use of multimedia consent modules?
 1. Never
 2. Rarely

3. Less than half of studies
 4. More than half of studies
 5. Almost every application
19. Has your IRB previously encountered the use of electronic signatures for documentation of informed consent?
1. Never
 2. Rarely
 3. Less than half of studies
 4. More than half of studies
 5. Almost every application

References

- Armstrong N, Dixon-Woods M, Thomas A, Rusk G, and Tarrant C. 2012 Do informed consent documents for cancer trials do what they should? A study of manifest and latent functions. *Sociology of Health and Illness* 34(8): 1230–1245. [PubMed: 22443456]
- Ballard HO, Shook LA, Iocono J, Bernard P, and Hayes D, Jr. 2011 Parents' understanding and recall of informed consent information for neonatal research. *IRB* 33(3): 12–19. [PubMed: 21736138]
- Batuyong E, Birks C, and Beischer AD. 2012 The use of multimedia as an adjunct to the informed consent process for ankle ligament reconstruction surgery. *Foot & Ankle Specialist* 5(3): 150–159. [PubMed: 22441499]
- Beamond BM, Beischer AD, Brodsky JW, and Leslie H. 2009 Improvement in surgical consent with a preoperative multimedia patient education tool: A pilot study. *Foot & Ankle International* 30(7): 619–626. [PubMed: 19589307]
- Bhutta ZA 2004 Beyond informed consent. *Bulletin of the World Health Organization* 82(10): 771–777. [PubMed: 15643799]
- Coletti AS, Heagerty P, Sheon AR, et al. 2003 Randomized, controlled evaluation of a prototype informed consent process for HIV vaccine efficacy trials. *Journal of Acquired Immune Deficiency Syndromes* 32(2): 161–169. [PubMed: 12571526]
- Cornioi A, Beischer AD, Donnan L, Graves S, and de Steiger R. 2011 Multimedia patient education to assist the informed consent process for knee arthroscopy. *ANZ Journal of Surgery* 81(3): 176–180. [PubMed: 21342392]
- De Vries R, DeBruin DA and Goodgame A. 2004 Ethics review of social, behavioral, and economic research: Where should we go from here? *Ethics & Behavior* 14(4): 351–368. [PubMed: 16625729]
- DHHS. 1979 The Belmont Report. Available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> (accessed March 27, 2014.)
- DHHS. 1979 (amend. 2009 Jan 15). 45 C.F.R. Part 46. Available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> (accessed March 28, 2014.)
- DHHS. n.d.. Federal Policy for the Protection of Human Subjects ('Common Rule'). Available at: <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> (accessed March 28, 2014.)
- Emanuel EJ, Wood A, Fleischman A, et al. 2004 Oversight of human participants research: Identifying problems to evaluate reform proposals. *Annals of Internal Medicine* 141(4): 282–291. [PubMed: 15313744]
- FDA. 2015 Use of electronic informed consent in clinical investigations questions and answers guidance for industry DRAFT GUIDANCE. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf> (accessed March 11, 2014.)

- Fink AS, Prochazka AV, Henderson WG, et al. 2010 Enhancement of surgical informed consent by addition of repeat back: A multicenter, randomized controlled clinical trial. *Annals of Surgery* 252(1): 27–36. [PubMed: 20562609]
- Foradori MA, and Nolan MT. 2012 Effect of a study map intended to support informed consent in transplant research. *Progress in Transplantation* 22(1): 56–61. [PubMed: 22489444]
- Juraskova I, Butow P, Lopez AL, et al. 2007 Improving informed consent in clinical trials: Successful piloting of a decision aid. *Journal of Clinical Oncology* 25(11): 1443–1444; author reply 1444. [PubMed: 17416867]
- Mason SA, and Allmark PJ. 2000 Obtaining informed consent to neonatal randomised controlled trials: Interviews with parents and clinicians in the euricon study. *The Lancet* 356(9247): 2045–2051.
- May T, Craig JM, and Spelley R. 2007 Viewpoint: Irb, hospital ethics committees, and the need for “translational informed consent”. *Academic Medicine* 82(7): 670–674. [PubMed: 17595563]
- Mexas F, Efron A, Luiz RR, Cailleaux-Cezar M, Chaisson RE, and Conde MB. 2014 Understanding and retention of trial-related information among participants in a clinical trial after completing the informed consent process. *Clinical Trials* 11(1): 70–76. [PubMed: 24296322]
- Migden M, Chavez-Frazier A, and Nguyen T. 2008 The use of high definition video modules for delivery of informed consent and wound care education in the mohs surgery unit. *Seminars in Cutaneous Medicine and Surgery* 27(1): 89–93. [PubMed: 18486030]
- NHLBI. 2011 How do I develop consent forms and who reviews them? Available at: https://www.nhlbi.nih.gov/crg/funding_consent.php (accessed March 28, 2014.)
- Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, and McCormick JB. 2013 Improving understanding in the research informed consent process: A systematic review of 54 interventions tested in randomized control trials. *BMC Medical Ethics* 14: 28. [PubMed: 23879694]
- OHRP. 2016 Informed Consent FAQs. Available at: <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/Informed-Consent/index.html> (accessed July 31, 2016.)
- Prochazka AV, Fink AS, Bartenfeld D, et al. 2014 Patient perceptions of surgical informed consent: Is repeat back helpful or harmful? *Journal of Patient Safety* 10(3): 140–145. [PubMed: 24522223]
- Rowbotham MC, Astin J, Greene K, and Cummings SR. 2013 Interactive informed consent: Randomized comparison with paper consents. *PLOS ONE* 8(3): e58603. [PubMed: 23484041]
- Sato K, Watanabe T, Katsumata N, Sato T, and Ohashi Y. 2014 Satisfying the needs of Japanese cancer patients: A comparative study of detailed and standard informed consent documents. *Clinical Trials* 11(1): 86–95. [PubMed: 24408900]
- Sonne SC, Andrews JO, Gentilin SM, et al. 2013 Development and pilot testing of a video-assisted informed consent process. *Contemporary Clinical Trials* 36(1): 25–31. [PubMed: 23747986]
- Spelley R, and May T. 2012 More than cheating: Deception, IRB shopping, and the normative legitimacy of IRB. *The Journal of Law, Medicine & Ethics* 40(4): 990–996.
- Tamariz L, Palacio A, Robert M, and Marcus EN. 2013 Improving the informed consent process for research subjects with low literacy: A systematic review. *Journal of General Internal Medicine* 28(1): 121–126. [PubMed: 22782275]
- White CS, Mason AC, Feehan M, and Templeton PA. 1995 Informed consent for percutaneous lung biopsy: Comparison of two consent protocols based on patient recall after the procedure. *American Journal of Roentgenology* 165(5): 1139–1142. [PubMed: 7572491]

Table 1.

Characteristics of Institutional Review Boards Chairpersons responding to the survey. Percents are column percents, numbers provided in parentheses.

	Medical/Public Health School	University	Hospital	Independent	Government
IRB Type					
<i>Biomedical</i>	96.0% (24)	64.5% (40)	100.0% (23)	100.0% (5)	100% (1)
<i>Social/Behavioral</i>	4.0% (1)	35.5% (22)	0.0% (0)	0.0% (0)	0.0% (0)
IRB Accredited					
	88.0% (22)	74.2% (46)	69.6% (16)	60% (3)	100% (1)
Active Studies under IRB Review					
<i><100</i>	4.0% (1)	4.8% (3)	0.0% (0)	0.0% (0)	100% (1)
<i>100–250</i>	8.0% (2)	8.1% (5)	8.7% (2)	0.0% (0)	0.0% (0)
<i>251–500</i>	0.0% (0)	21% (13)	4.3% (1)	20.0% (1)	0.0% (0)
<i>501–1000</i>	32.0% (8)	9.7% (6)	34.8% (8)	80.0% (4)	0.0% (0)
<i>>1000</i>	56.0% (14)	56.5% (35)	52.2% (12)	0% (0)	0.0% (0)
Average Consent Document Length					
<i><10 pages</i>	28.0% (7)	40.3% (25)	8.7% (2)	0% (0)	100% (1)
<i>10–15 pages</i>	32.0% (8)	33.9% (21)	30.4% (7)	60.0% (3)	0.0% (0)
<i>16–20 pages</i>	36.0% (9)	17.7% (11)	47.8% (11)	40.0% (2)	0.0% (0)
<i>21–25 pages</i>	4.0% (1)	6.5% (4)	8.7% (2)	0.0% (0)	0.0% (0)
<i>>25 pages</i>	0.0% (0)	1.6% (1)	4.3% (1)	0.0% (0)	0.0% (0)
Does IRB Assess Consent Document Reading Level?					
<i>Not Required</i>	72.0% (18)	74.2% (46)	56.5% (13)	80.0% (4)	100% (1)
<i>Less than half</i>	8.0% (2)	9.7% (6)	17.4% (4)	20.0% (1)	0.0% (0)
<i>More than half</i>	12.0% (3)	8.1% (5)	13.0% (3)	0.0% (0)	0.0% (0)
<i>Required for all</i>	8.0% (2)	8.1% (5)	13.0% (3)	0.0% (0)	0.0% (0)
Does IRB Assess Comprehension?					
<i>Never</i>	34.8% (8)	40.7% (22)	25% (5)	60.0% (3)	100% (1)
<i>Rarely</i>	43.5% (10)	38.9% (21)	35% (7)	40.0% (2)	0.0% (0)
<i>Less than half</i>	17.4% (4)	14.8% (8)	40% (8)	0.0% (0)	0.0% (0)
<i>More than half</i>	0% (0)	3.7% (2)	0.0% (0)	0.0% (0)	0.0% (0)
<i>Almost all</i>	4.3% (1)	1.9% (1)	0.0% (0)	0.0% (0)	0.0% (0)

Table 2.

Frequency of issues encountered by IRBs during the review of proposals involving human subjects research. Percents are row percents, numbers provided in parentheses.

Issues Encountered	Never	Rarely	Less than half of studies	More than half of studies	Almost every study
The focus is largely on written documentation rather than on ensuring that potential participants understand the entire research process.	15.5% (16)	21.4% (22)	15.5% (16)	23.3% (24)	24.3% (25)
The written documentation process and the language used are based on a desire to provide legal protection to researchers and sponsors of the research rather than to provide information to participants.	27.2% (28)	38.8% (40)	12.6% (13)	13.6% (14)	7.8% (8)
The information provided under various items in the informed consent process, such as sponsorships, funding, assured benefits, and risks, is excessive.	10.7% (11)	43.7% (45)	20.4% (21)	15.5% (16)	9.7% (10)
The consent document is lengthy and complex.	1.9% (2)	11.7% (12)	28.2% (29)	39.8% (41)	18.4% (19)
The consent document is higher than an 8th grade comprehension/reading level.	3.9% (4)	17.5% (18)	32.0% (33)	35.9% (37)	10.7% (11)
IRB Members disagree on the best means of providing information to ensure that the potential participants truly understand the nature of the research and the possible risks and benefits.	2.9% (3)	53.4% (55)	32.0% (33)	8.7% (9)	2.9% (3)
Alternative methods of obtaining consent, such as recorded or witnessed consent using third parties or community representatives, are used.	18.4% (19)	65.0% (67)	14.6% (15)	1.9% (2)	0.0% (0)