

Informed Consent Review

Ways to improve the consent process and a discussion of
substantive/editorial changes to the form

IRB Member Training April, 2018

6 Approaches to Increase Participant Comprehension

- ▶ Ensuring participants have appropriate knowledge of a study is a crucial goal of the informed consent process.
- ▶ A recent Quorum White Paper (Informed Consent: 6 Approaches To Increase Participant Comprehension, 02/02/16) outlines research-based approaches for improving informed consent and supporting participants' understanding of the studies they are asked to join.

1. Apply health literacy best practices to consent forms

- ▶ “Less unnecessary information, simpler vocabulary, bullets, larger font, other formatting”
- ▶ “Less redundant material, text reorganized, simpler writing, graphics, focus groups”
- ▶ “Simplified text in booklet format with color. 7th grade reading level”
- ▶ “Simplified paper document developed by a working group of clinical research nurse, IRB member, and healthy volunteer”
- ▶ “Simplified paper document developed by a working group and by systematic readability improvement”
- ▶ “Simplified paper document with revised layout, text styling, and language”

1. Apply health literacy best practices to consent forms

- ▶ Not all simplified and reformatted consent forms in participant comprehension, while some seem to only result in modest improvements.
- ▶ More investigation is needed on how to best streamline, redesign, and use consent forms so that they consistently improve the informed consent discussion and participant comprehension (across all literacy levels and cultures).

- Flory, J., & Emanuel, E. (2004). Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review. *JAMA: Journal of the American Medical Association*, 292(13), 1593–1601.
- Nishimura, A., Carey, J., Erwin P.J., Tilburt, J.C., Murad, M., & McCormick, J. (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). doi:10.1186/1472-6939-14-28.
- Freer, Y., McIntosh, N., Teunisse, S., Anand, K. J. S., & Boyle, E. M. (2009). More Information, Less Understanding: A Randomized Study on Consent Issues in Neonatal Research. *Pediatrics*, 123(5), 1301-1305. doi: 10.1542/peds.2007-3860.
- Montalvo, W. & Larson, E. (2014). Participant Comprehension of Research for Which They Volunteer: A Systematic Review. *Journal of Nursing Scholarship*, 46(6), 423-431. doi: 10.1111/jnu.12097.
- Flory, J. et al., 2004.
- Nishimura, A. et al., 2013.

2. Emphasize the informed consent discussion

- ▶ Research indicates that discussions between prospective participants and research staff (or independent educators) are potentially more effective than any other intervention in improving participant comprehension during the informed consent process.
- ▶ Effective discussions described in literature include:
 - ▶ A 30-minute phone call with a nurse
 - ▶ Repetition of information about the study
 - ▶ More meetings with research staff
 - ▶ Discussions structured with a questionnaire intended to promote comprehension of the research objectives, design, procedures, and
 - ▶ the consent process itself

- Nishimura, A. et al. (2013).
- Flory, J. et al. (2004).
- Nishimura, A. et al. (2013).

3. Use teach-back

- ▶ Teach-back—asking prospective participants to discuss the study in their own words—may allow for gauging comprehension and identifying gaps in participants' understanding.
- ▶ “Can you describe the study in your own words?”
- ▶ “Do you have any questions about the purpose of the study?”
- ▶ Teach-back could inform the researcher what a prospective participant does and does not know.

- Montalvo, W. et al. (2014).
- Cordasco, K. (2013). Chapter 39, Obtaining Informed Consent From Patients: Brief Update Review. Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Evidence Reports/Technology Assessments, No. 211. Agency for Healthcare Research and Quality. Retrieved from <http://www.ncbi.nlm.nih.gov/books/NBK133402/>
- Aldoory, L. et al. (2014).
- Kripalani, S., Bengtzen, R., Henderson, L.E., & Jacobson, T.A. (2008). Clinical research in low-literacy populations: Using teach-back to assess comprehension of informed consent and privacy information. *IRB: Ethics and Human Research* (30)2, 13–19.
- Aldoory, L. et al. (2014).

4. Develop awareness of health literacy levels, and shape communication on the assumption that participants may have low literacy

- ▶ About 30 million Americans have below-basic literacy.
- ▶ Individual studies and overviews of research on informed consent interventions suggest that low literacy can hamper understanding of a study even when efforts are made to improve the consent document or process.
- ▶ Specific populations can have unique needs: For example, researchers have recommended evaluating participants' health literacy before consent for glaucoma research with the Rapid Assessment of Adult Literacy in Medicine (REALM), in part because that condition impacts an age group that studies have associated with low health literacy.
- ▶ Regardless of the study condition or population, laypersons are potentially unacquainted with concepts such as placebo, randomization, voluntariness, and the differences between the nature of research and the nature of standard, therapy-oriented health care. Communication that emphasizes these concepts in an accessible way can pave the way to truly informed consent.

- National Center for Education Statistics. (2003). National Assessment of Adult Literacy. Retrieved from https://nces.ed.gov/naal/kf_demographics.asp#1
- Montalvo, W. et al. (2014).
- Muir, K.W. & Lee, P.P. (2009). Literacy and Informed Consent: Case for Literacy Screening in Glaucoma Research. *Arch Ophthalmol.* (127)5, 698–699. doi:10.1001/archophthalmol.2009.59

5. Leverage tools and techniques that studies show can improve patient comprehension

- ▶ The use of decision aids and informational supplements has improved patient comprehension for standard-of-care procedures
- ▶ Although not enough research has been conducted, experts believe that these tools can help in research settings.
- ▶ Research is moving toward more interactive consent form formats that support individual readers' information preferences and needs—such as tiered consent forms and eConsent.

- Stacey, D., Légaré, F., Col, N.F., Bennett, C.L., Barry, M.J., Eden, K.B., Holmes-Rovner, M., Llewellyn-Thomas, H., Lyddiatt, A., Thomson, R., Trevena, L., Wu, J.H. (2014). Decision aids for people facing health treatment or screening decisions. *Cochrane DatabaseSyst Rev.* 28:1:CD001431. doi: 10.1002/14651858.CD001431.pub4.
- Cordasco, K. (2013).
- Aldoory, L. et al. (2014).
- Juraskova I., Butow, P., Bonner, C., Bell, M.L., Smith, A.B., Seccombe, M., Boyle, F., Reaby L., Cuzick J., & Forbes J.F. (2014). Improving decision making about clinical trial participation – a randomised controlled trial of a decision aid for women considering participation in the IBIS-II breast cancer prevention trial. *British Journal of Cancer*, 111(1), 1–7. doi: 10.1038/bjc.2014.144.

6. Trust and support research staff

- ▶ Ensure that research team members have the time, support, resources, and training they need to understand a given protocol as well as prepare for and conduct informed consent discussions.
- ▶ Solicit feedback from experienced research staff—as subject matter experts—to effectively streamline consent forms and advise on how to enhance the informed consent process.
- ▶ An improved informed consent process can never be a reality without involvement of the research staff who ultimately facilitate it.

Substantive vs. Editorial Changes

What Must be Raised in the IRB Meeting?

Why does this issue of Substantive Changes Matter?

OHRP Compliance Activities: Common Findings of Non-Compliance & Guidance

- ▶ The Basis for requiring changes or approving/disapproving research were not documented in the minutes
- ▶ A discussion of controverted issues and their resolution were not documented in the minutes
- ▶ The IRB frequently approved research contingent on substantive modifications/clarifications directly relevant to the IRB criteria for approval under 45 CFR 46.111 without requiring additional review by the convened IRB.

Substantive Changes must be raised and documented:

- ▶ Convened Board must discuss all controverted issues and vote on requested changes
- ▶ This discussion and the rationale for the changes requested must be documented in the IRB minutes
- ▶ Reviewers SHOULD contact investigators prior to the meeting to ask questions. Reviewers SHOULD NOT ask investigators to make changes to documents prior to the meeting. These changes must be voted on by the Board.
- ▶ If the changes requested relate to one of the criteria for IRB approval this could result in the tabling of a protocol
- ▶ Must have all substantive issues raised so the Board can make an informed decision

What Items are Strictly Editorial and can be supplied on marked documents only?

- Identification of specific terms in the consent form that need to be replaced with lay language
- Abbreviations in the consent form that should be spelled out
- Deletion of text that appears elsewhere in the document
- Spelling errors that affect the readability of the informed consent document
- Moving current text that is appropriate from one section to another

** PLEASE NOTE: If you are supplying a marked consent or reviewer worksheet, please make a general statement in the meeting regarding the editorial changes that are being supplied (e.g. "A marked consent will be supplied that includes terms that must be changed to lay language")

Substantive vs. Editorial?

Please revise the risk section to include all risks of the study drug as outlined in the full protocol.

Substantive

Raise in the Meeting? YES!

Why? The rationale for this requested change must be documented in the minutes. The Board must decide if the reviewer's recommendation to add in the risks as listed in the protocol is appropriate and will satisfy the requirements for consent.

Substantive or Editorial?

Please explain the term “pharmacogenetics”
in lay language.

Editorial

Raised in Meeting: No!

Why: This change is editorial and can be provided in the marked consent only. Please note in the meeting that a marked consent form will be provided which requests that scientific terminology be replaced with lay terms.

Substantive or Editorial?

Please clarify why pregnant women are excluded from this study.

Substantive

Raised in Meeting? YES!

Why? This issue is substantive and may affect the Board's decision as to whether this study is approvable as it directly relates to one of the required elements for approval (Subject selection is equitable).

A Twist: The Reviewer determines that the rationale for the exclusion of pregnant women was provided in the protocol and is reasonable, but the consent does not specifically state that pregnant women are excluded. The reviewer requests that this information be added to the consent. Is this substantive or editorial?

Substantive

Raised in Meeting: Yes!

Why: The Board must document in the discussion that while it is clear in the protocol why pregnant women are excluded and this is appropriate, this information must be clearly stated in the consent form. This is also a substantive change because it relates to whether the consent is approvable.

Helpful Hints

- Please continue to supply marked consent forms/other notes (Chair, Primary/Secondary Reviewers only)
 - If you are not the Chair or the Primary/Secondary Reviewer and the reviewers do not mention a substantive change, please raise this in the meeting!
- Review your notes before the meeting and make a list of all items that should be raised during the meeting (do not rely on simply using your marked consent form)
- If you are supplying editorial changes, please note this in the meeting
- **When in Doubt, Shout it Out!**
 - It is always better to raise an issue even if you are unsure whether it is substantive
 - Do not feel pressured by time constraints to avoid raising items in the meeting

Reference: OHRP Findings of Non-Compliance

1. HHS regulations at 45 CFR 46.115(a)(2) require that minutes of IRB meetings be in sufficient detail to show the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. We have determined that minutes of IRB meetings failed to meet these requirements.
2. Contingent Approval of Research with Substantive Changes and no Additional Review by the Convened IRB. We have determined that the IRB frequently approved research contingent upon substantive modifications or clarifications that were directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111 without requiring additional review by the convened IRB. We have noted that when the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that the IRB needs in order to make the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB of responsive material, unless the research is eligible for review under an expedited review procedure.