E&HR

IRB Policies for Obtaining Informed Consent from Non-English-Speaking People

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Table 1.
Ranking according to Funding by the National Institutes of Health (NIH)

Organization	*2018 NIH funding*[1]	*Percentage of non-English speakers in the organization's immediate vicinity*[2]
1. Johns Hopkins University (Baltimore, MD)	$674,583,550	8%
2. University of California (San Francisco, CA)	$647,880,065	40%
3. University of Michigan (Ann Arbor, MI)	$552,433,992	21%
4. University of Pittsburgh (Pittsburgh, PA)	$536,502,831	10%
5. University of Pennsylvania (Philadelphia, PA)	$511,419,097	21%
6. Stanford University (Stanford, CA)	$505,474,358	47%
7. Washington University (Saint Louis, MO)	$486,295,442	9%
8. Duke University (Durham, NC)	$475,338,515	18%
9. Massachusetts General Hospital (Boston, MA)	$465,776,958	34%
10. Columbia University Health Sciences (New York, NY)	$464,799,343	45%
11. University of California, San Diego (La Jolla, CA)	$459,093,333	34%
12. University of Washington (Seattle, WA)	$455,841,035	20%
13. Yale University (New Haven, CT)	$454,012,666	21%
14. University of North Carolina (Chapel Hill, NC)	$446,660,231	16%
15. University of California, Los Angeles (Los Angeles, CA)	$409,733,609	55%
16. Brigham And Women's Hospital (Boston, MA)	$388,928,321	34%
17. Emory University (Atlanta, GA)	$350,444,625	9%
18. Icahn School of Medicine at Mount Sinai (New York, NY)	$345,221,510	45%
19. University of Wisconsin (Madison, WI)	$320,220,010	14%
20. Fred Hutchinson Cancer Research Center (Seattle, WA)	$305,514,929	20%
21. Northwestern University (Chicago, IL)	$304,846,861	37%
Total	$9,561,021,281	

[1] This data is available via "Research Portfolio Online Reporting Tools (RePORT)," National Institutes of Health, https://www.report.nih.gov.

[2] This is based on data from Data USA, accessed February 23, 2019, at https://datausa.io.

Table 2.
Theme Analysis

Themes	*Policy*	*Examples of policy language*[1]
Short form	**No. (%)**	
The short form is presumed acceptable.	1 (5%)	
The short form is acceptable in limited circumstances.	20 (95%)	"occasional and unexpected enrollment" "occasionally recruiting NES subjects" "very unusual circumstance where there is a window of opportunity for benefit to proposed subject"
Value statement		
There is a value statement discouraging the use of the short form.	5 (24%)	"use of translated full consent form is preferable" "strongly encouraged" "use of short form is strongly discouraged" "routine use not permitted"
Translation of documents		
Translated short-form templates are available.	17 (81%) yes	"The IRB has approved translations of the short form document in several languages. These approved translations are posted on the IRB website. If you require a short form consent in a different language, you must ha have the English version short form translated into the required language and submit it, with a Certificate of Translation, to the IRB for approval."
	2 (10%) no mention	
	1 (5%) only Spanish	
	1 (5%) no	
Certified or back are translations required.	15 (71%) yes	"forward and back translations of the consent form by two different individuals"
	6 (29%)	"A professional translator translates into their primary language or has the material proofread by a native speaker, works with a proofreader, has specific training in translation, has experience in translating and in the subject area addressed by the document, and can provide you a sample of their work, All translators listed in the appendix meet these criteria."

[1] These are direct quotations from web-accessible IRB policies and may appear in more than one document and at multiple institutions.

Themes	*Policy*	*Examples of policy language*[1]
Interpreter qualifications		
A certified professional interpreter is required.	11 (52%)	"The medical interpreters available through Interpreter Services are qualified by training and experience to interpret oral presentations of medical information to patients in clinical settings. Medical interpreters are tested and trained in the following: oral and written fluency in English and at least one other language; interpreting skills and cultural competencies; medical terminology; national standards of practice for medical interpreters; national interpreters code of ethics; department of hospital policies and procedures; HIPAA [Health Insurance Portability and Accountability Act]."
A "qualified" interpreter is acceptable with a general standard mentioned.	8 (38%)	"An impartial person of high health literacy in both English and the other language" "Someone with fluency in both English and the other language and who understands both cultures"
No mention is made of interpreter qualifications.	2 (10%)	
Casual interpretation		
A family member may serve as an interpreter.	14 (66%) no	"Interpreter may **not** be a family member of the participant." "Family members or friends of the subject, research coordinators, etc., are not permitted to serve as interpreters under this policy."
	2 (10%) yes	"Interpreter may be a member of the research team, a family member, or a friend of the participant."
	5 (24%) no mention	
A study team member may serve as an interpreter.	6 (29%) yes	"If a member of the study staff speaks the participant's language, the staff member can act as interpreter."
	3 (14%) no	"Interpreter may not be a member of the study team."
	12 (57%) no mention	
Duration of services		
Interpreters and translation are required for the entire study.	10 (48%) yes	"A qualified interpreter will need to be available during the consent process, and to answer questions and conduct procedures during the study." "[A]n interpreter will be necessary to facilitate the conversation during the consent process and communication throughout the course of the study."
	11 (52%) no mention	

[1] These are direct quotations from web-accessible IRB policies and may appear in more than one document and at multiple institutions.

Table 3.
Ethical Discussion

"Subject safety must not be endangered due to language barrier" (University of San Francisco, http://irb.ucsf.edu/consenting-non-english-speakers).
"If the subject does not clearly understand the information presented, subject consent will not be truly informed and may not be legally effective" (University of Michigan [Ann Arbor], https://az.research.umich.edu/medschool/guidance/research-and-non-english-speaking-or-reading-subjects).
"The criteria for IRB approval, 45 CFR 46.111(a) and/or 21 CFR 56.111, requires an equitable selection of participants in the conduct of research. This requirement stems from the principle of justice which requires that no group is unduly burdened or will benefit unfairly from research" (Stanford University, http://researchcompliance.stanford.edu/hs/new/resources/consent/non_english.html).
"To ensure that the principle of justice enunciated in the *Belmont Report* is adhered to, the IRB may require efforts to recruit individuals who are not fluent in English in research studies that offer the potential for therapeutic benefit" (Columbia University, https://research.columbia.edu/sites/default/files/content/HRPO/Nonenglishspeakingsubjects.Revised.FINAL%20111909.pdf).
"As part of each consent discussion, the researcher has an ethical and legal obligation to assess (informally or otherwise) the subject's understanding of the consent information to ensure that consent is truly informed" (University of Washington [Seattle], https://www.washington.edu/research/policies/sop-consent-documentation-2/).
"In order to meet one of the three primary ethical principles of equitable selection in the *Belmont Report*, non-English-speaking participants may not be routinely excluded from research" (Stanford University, http://researchcompliance.stanford.edu/hs/research/documents/GUI03H23%20Non-English%20speaking%20participants.pdf).
"*The Belmont Report* identifies 'justice' and 'respect for persons' as two fundamental ethical principles that must underlie the conduct of all human subjects research. The principle of justice requires that the burdens and benefits of research are equitably distributed. The principle of respect for persons requires that 'adequate standards for informed consent are satisfied' so that subjects are provided with sufficient meaningful information to decide whether they want to enroll in a research study" (Icahn School of Medicine [New York], https://icahn.mssm.edu/files/ISMMS/Assets/Research/PPHS/Policy%20%20Nonenglishspeakingsubjects.pdf).