

INNOVATIONS IN INFORMED CONSENT: A REVIEW OF EMPIRICAL RESEARCH
EMILY E. ANDERSON, LOYOLA UNIVERSITY CHICAGO
JULY 28, 2015

REFERENCE LIST

Agre P, Rapkin B. (2003). Improving informed consent: A comparison of four consent tools. *IRB: Ethics and Human Research*, 25(6): 1-7.

Appelbaum PS, Lidz CW, Klitzman R. (2009). Voluntariness of consent to research: A preliminary empirical investigation. *IRB*, 30(6): 10-14.

Antoniou EE, Draper H, Reed K, Burls A, Southwood TR, Zeegers MP. (2011). An empirical study on the preferred size of the participant information sheet in research. *Journal of Medical Ethics*, 37(9): 557-562.

Bentley JP, Thacker PG. (2004). The influence of risk and monetary payment on the research participation decision-making process. *Journal of Medical Ethics*, 30: 293-298.

Brehaut JC, Lott A, Fergusson DA, Shojania KG, Kimmelman J, Saginur R. (2009). Can patient decision aids help people make good decisions about participating in clinical trials? A study protocol. *Implementation Science*, 3:38.

Brehaut JC, Fergusson DA, Kimmelman J, Shojania KG, Saginur R, Elwyn G. (2010). Using decision aids may improve informed consent for research. *Contemporary Clinical Trials*, 31: 218-220.

Brehaut JC, Carroll K, Elwyn G, Saginur R, Kimmelman J, Shojania K, Syrowatka A, Nguyen T, Fergusson D. (2015). Elements of informed consent and decision quality were poorly correlated in informed consent documents. *J Clin Epidemiology*, epub ahead of print.

Brown RF, Shuk E, Butow P, Edgeron S, Tattersall MHN, Ostross JS. (2011) Identifying patient information needs about cancer clinical trials using a question prompt list. *Patient Education and Counseling*, 84: 69-77.

Burris S, Moss K. (2006). US health researchers review their ethics review boards: A qualitative study. *JERHRE*, 39-58.

Casarett D, Karlawish J, Asch DA. (2002). Paying hypertension research subjects: Fair compensation or undue inducement? *Journal of General Internal Medicine*, 17:651-653.

Denzen EM et al. (2012). Easy-to-read informed consent forms for hematopoietic cell transplantation in clinical trials. *Biol Blood Marrow Transplant*, 18(12): 183-189.

Dickert N, Emanuel E, Grady C. (2002). Paying research subjects: An analysis of current policies. *Annals of Internal Medicine*, 136: 368-373.

DuBois JM. (2008). Hidden data for research ethicists: An introduction to the concept and a series of papers. *Journal of Empirical Research on Human Research Ethics (JERHRE)*, 3(3): 3-5.

Falagas M, Korbil IP, Kondilis B, et al., (2009). Informed consent: How much and what do patients understand? *American Journal of Surgery*, 198: 420-435.

Festinger DS, Dugosh KL. (2012). Paying substance abusers in research studies: where does the money go? *Am J Drug Alcohol Abuse*, 38(1):43-8.

Geppert C., P. Candilis, S. Baker, C. Lidz, P. Appelbaum, and K. Fletcher. 2014. Motivations of patients with diabetes to participate in research. *AJOB Empirical Bioethics* 5(4): 14-21.

Halpern et al. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine*, 164:801-803.

Hazen

Jeste DV et al. (2009). Multimedia consent for research in people with schizophrenia and normal subjects: A randomized controlled trial. *Schizophrenia Bulletin*, 35(4): 719-729.

Kirkby HM, Calvert M, Draper H, Keeley T, Wilson S. (2012). What potential research participants want to know about research: A systematic review. *BMJ Open*, 2.

Madathil KC, Koikkara R, Dorlette-Paul M, Ranganayakulu S, Greenstein JS, Gramopadhye AK. (2012). An investigation of format modifications on the comprehension of information in consent form when presented on mobile devices. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*, 56: 921.

Madathil KC, Koikkara R, Gramopadhye AK, Greenstein JS. (2011). An empirical study of the useability of consenting systems: iPad, touchscreen and paper-based systems. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*, 55: 813.

Mamotte N, Wassenaar D. (2015). Measuring voluntariness of consent to research: An instrument review. *Journal of Empirical Research on Human Research Ethics*, 10(2):121-131.

Newman E., E. Risch, and N. Kassam-Adams. 2006. Ethical issues in trauma-related research: A review. *Journal of Empirical Research on Human Research Ethics* 1(3):29-46.

Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, and McCormic JB. (2013). Improving understanding in the research informed consent process: A systematic review of 54 interventions tested in randomized controlled trials. *BMC Medical Ethics*, 14:28.

Paasche-Orlow MK, Taylor HA, Brancan FL. (2003). Readability standards for informed consent as compared with actual readability. *NEJM*, 348(8):721-726.

Ryan RE, Prictor MJ, McLaughlin KJ, Hill SJ. (2008). Audio-visual presentation of information for informed consent for participation in clinical trials. *Cochrane Database Systematic Reviews*, 23 (1).

Sachs GA, Hougham GW, Sugarman J, et al. (2003). Conducting empirical research on informed consent: Challenges and questions. *IRB: Ethics & Human Research*, 25(5): S4-10.

Schmotzer GL. (2012). Barriers and facilitators to participation of minorities in clinical trials. *Ethnicity & Disease*, 22, 226-230.

Siminoff LA, Caputo M, Burant C. (2004). The promise of empirical research in the study of informed consent theory and practice. *HEC Forum*, 16(1): 53-71.

Singer E, Hippler HJ, Schwarz N. (1992). Confidentiality assurances in surveys: Reassurance or threat. *International Journal of Public Opinion Research*, 57: 465-482.

Singer E, Von Thurn DR, Miller ER. (1995). Confidentiality assurances and response: A quantitative review of the experimental literature. *Public Opinion Quarterly*, 59: 66-77.

Stevens T, Ahmedzia SH. (2004). Why do breast cancer patients decline entry into randomized trials and how do they feel about their decision later: a prospective, longitudinal, in-depth interview study. *Patient Education and Counseling*, 52: 341-348.

Sugarman J, McCrory DC, Powell D, et al. (1999). Empirical research on informed consent: An annotated bibliography. *Hastings Center Report*, 29: S1-S42.

Trauth JM, Musa D, Siminoff L, Jewell IK, Ricci E. (2000). Public attitudes regarding willingness to participate in medical research studies. *Journal of Health and Social Policy* 12(2): 23-43.
Wells 2012

Wendler D, Krohmal B, Emanuel EJ, Grady C, for the ESPRIT Group. (2008). Why patients continue to participate in clinical research. *Archives of Internal Medicine*, 168: 1294-1299.

Williams B, Irvine L, McGinnis AR, McMurdo MET, and Crombie IK. (2007). When “no” might not quite mean “no”; the importance of informed and meaningful non-consent: results from a survey of individuals refusing participation in a health-related research project. *BMC Health Services Research*, 7:59.