



Ethical Considerations in Acute Stroke Research

StrokeNet Grand Rounds 5/26/2022

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Background

Steneck NH. Introduction to the Responsible Conduct of Research. US Department of Health and Human Services. Office of Research Integrity. 2007.

<https://ori.hhs.gov/ori-introduction-responsible-conduct-research>

WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

Dittrich L. Patient H.M.: A Story of Memory, Madness, and Family Secrets. Random House. 2017.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Department of Health, Education, and Welfare. April 18, 1979.

https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

Decisional Capacity

Beauchamp TL, Childress JF. Principles of Biomedical Ethics, 7th ed. Oxford University Press; 2013.

Appelbaum PS, Grisso T. Assessing patients' capacities to consent to treatment. N Engl J Med. 1988;319(25):1635-1638.

Appelbaum PS, Grisso T. MacArthur Competence Assessment Tool for Clinical Research. Professional Resource Exchange; 2001.

Jeste DV, Palmer BW, Appelbaum PS, et al. A New Brief Instrument for Assessing Decisional Capacity for Clinical Research. Arch Gen Psychiatry. 2007;64(8):966–974.

Surrogate Decision-Making

Flaherty ML, Karlawish J, Khoury JC, et al. How important is surrogate consent for stroke research? *Neurology*. 2008 Nov 11;71(20):1566-71.

Kane I, Lindley R, Lewis S, Sandercock P; IST-3 Collaborative Group. Impact of stroke syndrome and stroke severity on the process of consent in the Third International Stroke Trial. *Cerebrovasc Dis*. 2006;21(5-6):348-52.

Exceptions from Informed Consent

Sattin JA, Chiong W, Bonnie RJ, et al. Consent Issues in the Management of Acute Ischemic Stroke: AAN Position Statement. *Neurology*. 2022 Jan 11;98(2):73-79.

Rebers S, Aaronson NK, van Leeuwen FE, Schmidt MK. Exceptions to the rule of informed consent for research with an intervention. *BMC Med Ethics*. 2016;17:9.

Bateman BT, Meyers PM, Schumacher HC, et al. Conducting stroke research with an exception from the requirement for informed consent. *Stroke*. 2003 May;34(5):1317-23.

U.S. Food and Drug Administration. Exception from Informed Consent Requirements for Emergency Research: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors. April 2013. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research>

Feldman WB, Hey SP, Kesselheim AS. A Systematic Review of the Food and Drug Administration's 'Exception From Informed Consent' Pathway. *Health Aff (Millwood)*. 2018 Oct;37(10):1605-1614.

Kompanje EJO, van Dijck JTJM, Chalos V, et al. Informed consent procedures for emergency interventional research in patients with traumatic brain injury and ischaemic stroke. *Lancet Neurol*. 2020 Dec;19(12):1033-1042.

Law ZK, Appleton JP, Scutt P, et al. Brief Consent Methods Enable Rapid Enrollment in Acute Stroke Trial: Results From the TICH-2 Randomized Controlled Trial. *Stroke*. 2022 Apr;53(4):1141-1148.

Rose DZ, Kasner SE. Informed consent: the rate-limiting step in acute stroke trials. *Front Neurol*. 2011 Oct 17;2:65.

Feldman WB, Kim AS, Josephson SA, Lowenstein DH, Chiong W. Effect of waivers of consent on recruitment in acute stroke trials: A systematic review. *Neurology*. 2016;86(16):1543-1551.