Resources

NATIONAL INSTITUTES OF HEALTH

GENERAL NIH GUIDELINES AND POLICIES

National Institutes of Health (NIH). NIH policy for data and safety monitoring. Bethesda, MD: National Institutes of Health; 1998 Jun 10. Report No.: NOT-98-084. Available from: https://grants.nih.gov/grants/guide/notice-files/not98-084.html.

NIH. Guidance on reporting adverse events to Institutional Review Boards for NIH-supported multicenter clinical trials. Bethesda, MD: National Institutes of Health; 1999 Jun 11. Report No.: NOT-99-107. Available from: https://grants.nih.gov/grants/guide/notice-files/not99-107.html.

NIH. Further guidance on a data and safety monitoring for phase I and phase II trials. Bethesda, MD: National Institutes of Health; 2000 Jun 5. Report No.: NOT-OD-00-038. Available from: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html.

Office of Inspector General. Data and Safety Monitoring Boards in NIH clinical trials: meeting guidance, but facing some issues. Washington DC: Department of Health and Human Services; Jun 2013. Report No.: OEI-12-11-00070. Available from: https://oig.hhs.gov/oei/reports/oei-12-11-00070.pdf.

INSTITUTE-SPECIFIC GUIDELINES AND POLICIES

The following NIH Institutes have specific DSM guidelines:

National Cancer Institute (NCI): http://deainfo.nci.nih.gov/grantspolicies/datasafety.pdf

National Center for Complementary and Integrative Health (NCCIH): http://nccih.nih.gov/research/policies/datasafety

National Eye Institute (NEI): https://nei.nih.gov/funding/policy/policy6

National Heart, Lung, and Blood Institute (NHLBI): http://www.nhlbi.nih.gov/funding/policies/dsmpolicy.htm

National Institute on Aging (NIA): http://www.nia.nih.gov/research/dea/implementation-policies-human-intervention-studies

National Institute on Alcohol Abuse and Alcoholism (NIAAA): http://www.niaaa.nih.gov/ResearchInformation/ExtramuralResearch/ResourcesAppGrantees/guidelines.htm

National Institute on Allergy and Infectious Diseases (NIAID): https://www.niaid.nih.gov/grants-contracts/human-subjects

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS): https://www.niams.nih.gov/grants-funding/conducting-clinical-research/data-safety-guidelines-policies

National Institute of Child Health and Human Development(NICHD): http://www.nidcd.nih.gov/research/clinicalstudies/Information-for-Researchers-and-Health-Professionals/Pages/NIDCD-Guidelines-for-Data-and-Safety-Monitoring-of-Clinical-Trials.aspx

National Institute on Deafness and Other Communication Disorders (NIDCD): https://www.nidcr.nih.gov/Research/ToolsforResearchers/Toolkit/DataandSafetyMonitoring.htm

National Institute of Dental and Craniofacial Research (NIDCR): http://www.nidcr.nih.gov/GrantsAndFunding/PoliciesandGuidance/ClinicalResearch/DataandSafetyMonitoring.htm

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): http://www.niddk.nih.gov/research-funding/process/human-subjects-research/policies-for-clinical-researchers/data-safety-monitoring-plans/Pages/data-and-safety-monitoring-plans.aspx

National Institute on Drug Abuse (NIDA): http://www.drugabuse.gov/Funding/DSMB-SOP.html

National Institute of Environmental Health Sciences (NIEHS): https://www.niehs.nih.gov/research/clinical/patientprotections/dsmb/index.cfm

National Institute of General Medical Sciences (NIGMS): https://www.nigms.nih.gov/Research/humansubjects/Pages/clinicaltrials.aspx

National Institute of Mental Health (NIMH): http://www.nimh.nih.gov/funding/clinical-research/nimh-policy-governing-the-monitoring-of-clinical-trials.shtml

National Institute of Neurological Disorders and Stroke (NINDS): https://www.ninds.nih.gov/Funding/Apply-Funding/Application-Support-Library/NINDS-Guidelines-Data-and-Safety-Monitoring

National Institute of Nursing Research (NINR): https://www.ninr.nih.gov/sites/www.ninr.nih.gov/files/NINR%20DSM%20Policy%202014%20FINAL.pdf

FOOD AND DRUG ADMINISTRATION

Food and Drug Administration (FDA). Guidance for clinical trial sponsors: establishment and operation of clinical trial data monitoring committees. Silver Spring, MD: Food and Drug Administration; 2006 Mar. 34 p. Report No.: OMB Control No. 0910-0581. Available from: https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm127073.pdf.

FDA. Guidance for clinical investigators, industry, and FDA staff: financial disclosure by clinical investigators. Silver Spring, MD: Food and Drug Administration; 2013 Feb. 35 p. Available from: https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf.

OFFICE FOR HUMAN RESEARCH PROTECTIONS

Office for Human Research Protections (OHRP). Unanticipated problems involving risks & adverse events guidance (2007). Washington DC: Department of Health and Human Services; 2007 [updated Mar 21, 2016]. Available from: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html.

OHRP. Continuing review guidance. Washington DC: Department of Health and Human Services; 2010 [updated Mar 18, 2016]. Available from: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html.

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Committee for Medicinal Products for Human Use. Guideline on data monitoring committees. London, UK: European Medicines Agency; 2005 Jul 27. Report No.: EMEA/CHMP/EWP/5872/03 Corr. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003635.pdf.

Efficacy guidelines. London, UK: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Available from: http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.

International Conference on Harmonisation (ICH). Structure and content of clinical study reports. Geneva, Switzerland: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; 1995 Nov 30. 41 p. Report No.: E3. Available from: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_Guideline.pdf.

ICH. Statistical principles for clinical trials. Geneva, Switzerland: International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; 1998 Feb 5. 39 p. Report No.: E9. Available from: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E9/Step4/E9_Guideline.pdf.

ICH. Integrated addendum to ICH E6(R1): guideline for good clinical practice. Geneva, Switzerland: International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; 2016 Nov 9. 66 p. Report No.: E6(R2). Available from: http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf.

Special Programme for Research and Training in Tropical Diseases. Operational guidelines for the establishment and functioning of Data and Safety Monitoring Boards. Geneva, Switzerland: World Health Organization; 2005 44 p. Report No.: TDR/GEN/Guidelines/05.1. Available from: http://www.who.int/tdr/publications/documents/operational-guidelines.pdf?ua=1.

FURTHER READING

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Tereskerz PM, Guterbock TM, Kermer DA, Moreno JD. An opinion and practice survey on the structure and management of data and safety monitoring boards. Accountability in research. 2011;18(1):1-30. PMID: 21287412.