Reading Materials and Resources

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FDA Information Sheet Guidances. Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors. www.fda.gov/oc/ohrt/irbs/default.htm

Investigational New Drug (IND) Application Process. http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm

Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

NIH Policy for Data and Safety Monitoring (Examples of Appropriate Types of Monitoring and Oversight for Different Types of Studies). http://grants.nih.gov/grants/guide/notice-files/NOT98-084.html

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