Regulatory Contact Information

Hope Research Institute of Phoenix, AZ, hands investigators a brief page of information about human subjects research regulations, regulatory agencies, and their contacts. Here's a sample of this tool:

• Patricia Adams, Managing Partner – HOPE Research Institute, LLC. Direct: 602.288-4681; Cell: 602.350-1192. Email: patricia.adams@hriaz.com

• Please refer to the "Code of Federal Regulations" and "ICH Guidelines" manuals that HOPE provided for questions concerning:

Regulatory Guidance

• Title 21 Code of Federal Regulations
• Part 50: Protection-Human Subjects
• Part 54: Financial Disclosure
• Part 56: Institutional Review Boards
• Part 312: IND
• Title 45 Code of Federal Regulations
• Part 46: HHS Protection of Human Subjects

Good Clinical Practice

• ICH Guidelines Good Clinical Practice
• The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

• Human Research Protections Program

HOPE Research Institute, LLC shall work to ensure the protection of human subject participants by defining a Human Research Protections Program in the policies defined by:

• HOPE Research Institute's SOP's;
• The Study Protections Policy Guide;
• The Contracts and Budgets Policy and Procedures Guide.

These documents are readily available to you at any time. Please ask your study coordinator and/or Patricia Adams to bring them to your attention.

• FDA: U.S. Food and Drug Administration
19900 MacArthur Blvd. Suite 300
Irvine, CA 92612-2445
(949) 798-7600

Websites:

• Food and Drug Administration (FDA) - http://www.fda.gov/
• Agency for Health Care and Research - http://www.ahcpr.gov
• Regulatory Affairs Professional Society - http://www.raps.org
• Association for Clinical Research (ACRP) - http://www.acrpnet.org