



NEWSLETTER

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Contact Information for IRB Company, Inc.

Email: irb@irbco.com
 Website: www.irbco.com
 Phone: 714-562-0526



What is Human Subject Research?

The Code of Federal regulations defines **Research** as:

"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)]
 and defines **Human Subjects** as:

"...living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." [45 CFR 46.102(f)(1-2)]

Exciting changes at IRB Company, Inc.

The IRB Company, Inc. is pleased to announce that we have added some new programs to better serve our clients' needs. We have a new Business Development department headed by our B.D. Director Roberta Sapone. The department can be reached at BD@irbco.com and can assist you with any questions regarding the services at IRB Company.

We also have started a new program to provide potential research subjects with more information through our Research Participant Outreach Program by inviting Investigators to participate. Our goal is to provide prospective research volunteers with a research brochure that would help them decide if participating in a research project is right for them or not.

If the Investigator is interested in joining us in this project, we will provide them with a set of brochures [*Becoming a Research Volunteer*] which can be displayed at the Investigators site in a clear brochure holder that will be provided to them at no cost. You can reach that department at their new email OutreachProgram@irbco.com.

IRB Company, Inc. Website and Company emails:

IRB Company, Inc. website contains useful information and has access to our electronic submission portal. The web address is www.irbco.com.

The following are our current department email addresses:

- Company email: irb@irbco.com
- Compliance Department: compliance@irbco.com
- Business Development: bd@irbco.com
- Research Participant Outreach Program: OutreachProgram@irbco.com

HHS Announces Proposal to Improve Rules Protecting Human Research Subjects

Changes under consideration would ensure the highest standards of protections for human subjects involved in research, while enhancing effectiveness of oversight.

The U.S. Department of Health and Human Services has announced that the federal government is contemplating various ways of enhancing the regulations overseeing research on human subjects. Before making changes to the regulations – which have been in place since 1991 and are often referred to as the Common Rule – the government is seeking the public's input on an array of issues related to the ethics, safety, and oversight of human research. The changes under consideration can be found in an Advance Notice of Proposed Rulemaking (ANPRM), *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*, published in the July 25 Federal Register. The proposed changes are designed to strengthen protections for human research subjects.