



# Human Subjects Protections Subcommittee for Reducing Regulatory Burden Update

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## Co-Chairs

Lois Brako, Assistant Vice President, University of Michigan

Jane McCutcheon, Associate Professor, New York University

Ann Hardy, NIH Extramural Human Research Protection Officer

May 5, 2011



## Goals

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- We seek to identify areas of human subjects research review that are often made overly burdensome by institutional policies, and to clarify what *is* required by the federal regulations.
- We also seek to provide effective practices and examples of how to meet regulations and protect human subjects while decreasing the administrative burden on researchers, IRB staff, IRB board members, and IOs.



## Communications/Networking

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- **Steering Committee, with consultants from OHRP, SACHRP, FDA, NSF, CoGR**
- **Working Group members = 25 and still growing**
- **ListServ (FDP-IRB-L@lsw.nas.edu) = 80**
- **Presented talks and workshops at OHRP, SACHRP, national PRIM&R meetings**
- **FDP Web site:**  
**[http://sites.nationalacademies.org/PGA/fdp/PGA\\_060999](http://sites.nationalacademies.org/PGA/fdp/PGA_060999)**



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## Human Subject Subcommittee

### Charge of the Subcommittee

Reviews existing and new administrative requirements imposed by federal regulations and program officers related to the human research participant protections. The emphasis should be on harmonization of requirements across federal agencies, reduction of redundancies and identifying good practices.

### Initiatives

- [Human Subjects Protections Demonstration Projects](#)
- [Practical Guide for Reducing Regulatory Burden](#)

### Documents

- Nature Article on [Human Subject Regulations](#) by Dr. Scott Kim, University of Michigan
- [Report on Research Compliance](#), April 2011 (Excerpt featuring FDP presentation to SACHRP on page 2)

[Listserv - FDP-IRB-L@lsw.nas.edu](#)

### Subcommittee Members



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## Current Projects

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- Practical Guide for Reducing Regulatory Burden
- Exemption Wizard Demonstration
- Harmonization Project



# Practical Guide for Reducing Regulatory Burden

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Work In Progress

- Guide Format:
  - Topic Background Info
  - Regulatory Flexibility
  - Effective Practices
  - Examples
  - Mini-Demonstrations and Roadmaps



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## PRACTICAL GUIDE FOR REDUCING REGULATORY BURDEN

Presented by the FDP Human Subjects Protections Subcommittee

### Table of Contents

- I. [Background: FDP Projects for Reducing Regulatory Burden](#)
- II. Is IRB Review Required?
  - a. Examples of Not-Regulated Research
  - b. What Constitutes "Engagement"?
  - c. QI/QA versus Research
- III. [Avoiding Over-review of Exempt Research](#)
  - a. [Examples of Exempt Research for Each Category](#)
  - b. [When Do Changes to Exempt Research Projects Require IRB Review?](#)
  - c. Ways to Make Your Study Exempt
- IV. Conserving IRB Resources
  - a. Staff Approval of Clerical Changes in Protocols
  - b. [Using Alternative IRB Models to Optimize Use of IRB Resources](#)
    - I. [Avoiding Duplicate Review by Using IRB Authorization Agreements](#)
    - II. Independent IRB Review
    - III. Facilitated IRB Review
    - IV. [NIH Alternative IRB Models Chart](#)