



# Reducing Regulatory Burden in Human Research

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- **Updates from the HS Subcommittee**
  - **Steering Committee**
  - **Action Plan**

**Co-Chairs:** Lois Brako, Jane McCutcheon, Ann Hardy  
May 13, 2010



# **Federal Demonstration Partnership (FDP)**

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## **Steering Committee**

### **Co-Chairs**

**Lois Brako, Director Research Regulatory Affairs, University of Michigan**

**Jane A. McCutcheon, Associate Professor, New York University**

**Ann Hardy, NIH Extramural Human Research Protection Officer**

### **Members**

**Elizabeth Bankert, Assistant Provost, Dartmouth College (SACHRP Rep)**

**Scott Kim, Professor, University of Michigan**

**Judy Neidig, Ohio State University, Director, Office of Responsible Research Practices**

**Sandra Schneider, Professor, University of Florida**

### **Consultants:**

**Carol Blum, Council on Government Relations (CoGR)**

**Phil Budashewitz, Clinical Research Policy Analysis and Coordination Program (Crapac)**

**Kelly Craig-Henderson, Human Subjects Research Protections Officer NSF**

**Julia Gorey and Ivor Pritchard, OHRP**

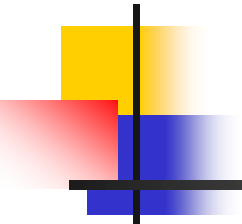


# Federal Demonstration Partnership (FDP)

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- **Proposed Projects**

- **Practical Guide for Reducing Regulatory Burden**
- **Continuing review modifications**
- **Exemptions – clarification and proposal of new categories**
- **Human subjects addendum to FDP subaward template**
- **Just-in-Time improvements**



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**Currently, many IRBs do not employ the flexibility allowed within federal regulations because they have not developed alternative processes or procedures to the standard review model.**

**The guide will strive to provide:**

- **Clarification of definitions of regulatory terms that currently cause confusion;**
- **Clear descriptions of criteria for application of regulations;**
- **Guidance for interpreting regulations;**
- **Examples of successful models for streamlining; and**
- **Detailed descriptions of procedures needed to implement change, when appropriate.**

**The FDP subcommittee will consult with OHRP and AAHRPP throughout the development of this project.**



## Other Projects

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### **Elimination or Modification of the Requirement for Annual Continuing Review for Minimal Risk Research**

- **Develop a checklist of the minimum information needed for continuing review of minimal risk research for inclusion in the Practical Guide**
- **Demonstration – greater than one year approvals  
(modeled after U-M's 2-Year approval Demonstration – see <http://www.hrpp.umich.edu/initiative/>)**



## Other Projects

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### Clarification of Existing and Proposal of New Exemption Categories

- Review existing categories and the SACHRP recommendations for clarification and develop guidance information for inclusion in the Practical Guide
- Demonstration- short form for exemption determination
- Demonstration - new exemption categories (modeled after U-M's Exemption 7 Demonstration – see <http://www.hrpp.umich.edu/initiative/>)
- Draft recommendations for new exemption categories

#### Examples:

- Certain kinds of minimal risk research
- Secondary analysis of identifiable data
- Man vs. machine projects



## Other Projects

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- Human Research Subaward Addendum

**Work with FDP's Contract Committee to develop an addendum for specific human research flow down provisions for subawards**

- Improvement to the Just-in-Time Process

**To be developed**