Reducing Regulatory Burden in Human Research

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

Co-Chairs: Lois Brako, Jane McCutcheon, Ann Hardy

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Federal Demonstration Partnership (FDP)

Steering Committee

Co-Chairs

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Federal Demonstration Partnership (FDP)

- **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**

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

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

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

- **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