

Federal Demonstration Partnership (FDP) Current Initiatives for Reducing Burden of Regulatory Compliance

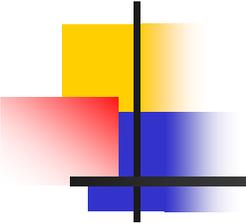
Lois Brako, Assistant Vice President, University of Michigan

Jane McCutcheon, Associate Professor, New York University

Ann Hardy, NIH Extramural Human Research Protection Officer

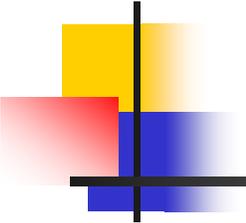
Elizabeth Bankert, Assistant Provost, Dartmouth College

March 8, 2011



Federal Demonstration Partnership (FDP)

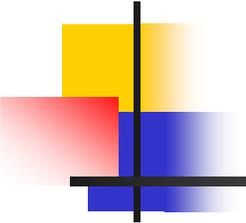
- Background about the FDP
- Goals of the Human Subjects Protection Subcommittee
 - Priority Projects
 - Current Progress
 - Practical Guide
 - Exemption Wizard
 - Harmonization Project
- Partnership with SACHRP
 - General Feedback and Guidance
 - Individual Participation
 - Institutional Participation



Federal Demonstration Partnership (FDP)

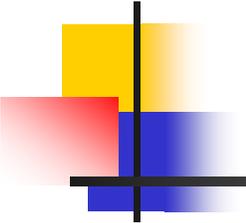
- **The Federal Demonstration Partnership** is a cooperative initiative among 10 federal agencies and about 120 institutional recipients of federal funds.
(<http://www.thefdp.org>)
- The FDP is a sponsored by the Government, University, Industry Research Round-table of the National Academies.
- Its purpose is to reduce the administrative burdens associated with research grants and contracts.





Federal Demonstration Partnership (FDP)

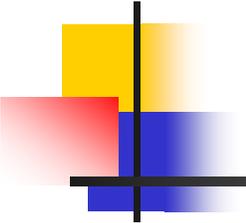
- The FDP's current initiatives to reduce regulatory burden while maintaining research accountability and compliance with federal regulations was shaped in large part by the 2007 [Faculty Burden Survey](#), conducted by the FDP Faculty Standing Committee.
- This survey of 6000 faculty researchers nationwide demonstrated a dramatic increase in the amount of time faculty members spent on administrative tasks related to their research, particularly in the case of [human subjects research](#), which in turn limits the amount of time available to conduct the research itself.



Research Compliance Committee (RCC)

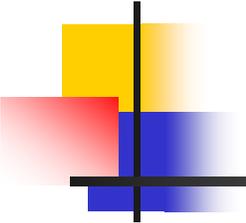
Charge

- Reviews existing and new administrative requirements imposed by federal regulations and program officers related to but not limited to the human research participant protections, animal use and care, conflicts of interest (individual and institutional), objectivity in research, and export controls. The emphasis should be on harmonization of requirements across federal agencies, reduction of redundancies, and identifying good practices.



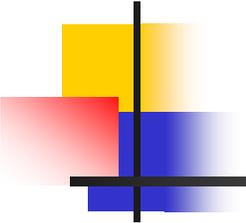
RCC Subcommittees

- Human Subjects Protections
- Animal Care and Use
- Conflict of Interest
- Export Controls



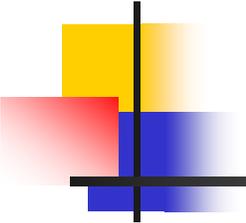
Human Subjects Protections Subcommittee Goals

- The Human Subjects Protections Subcommittee seeks to identify areas that are often overly burden by institutional policies and to describe what is required by the 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.



Consultants

- Federal
 - Regulatory – OHRP, FDA
 - Sponsors – NIH, NSF
 - Advisory – SACHRP
- IRB representatives
- Researchers
- Other groups
 - Council on Government Relations (CoGR)
 - AAHRPP
 - CTSA Regulatory Knowledge



Human Subjects Protections Steering Committee

Co-Chairs

Lois Brako, Assistant Vice President, 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)

Deborah Barnard, Director, Office of Research Compliance and Regulatory Affairs,
Children's Hospital of Philadelphia

Judy Birk, Director, IRB-Health Sciences and Behavioral Sciences, University of Michigan

Lauretta Gerrity, Associate VP for Research, University of Alabama at Birmingham

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)

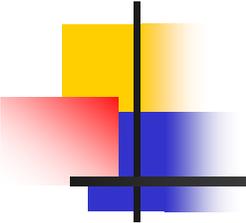
TBD, Clinical Research Policy Analysis and Coordination Program (CRpac)

Kelly Craig-Henderson, Human Subjects Research Protections Officer NSF

Julia Gorey and Ivor Pritchard, OHRP

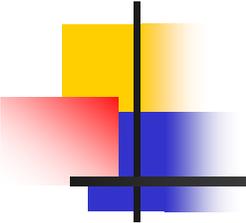
Scott Kim, Professor, University of Michigan

AAHRPP?



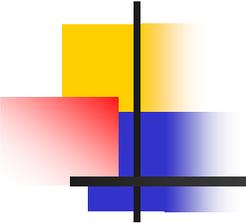
Sources of Inspiration

- FDP Faculty Burden Survey
- OHRP and FDA Guidance
- SACHRP recommendations (Over 70!)
- U–M Demonstrations (<http://www.hrpp.umich.edu/initiative/>)
- Publications (e.g. Illinois White Paper, Pruning the Regulatory Tree, Dr. Menikoff's articles and editorials)



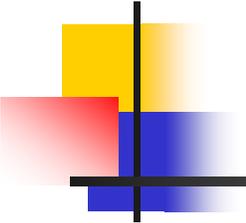
Proposed Priority Projects

- Practical Guide for Reducing Regulatory Burden
- Clarification of Existing and Proposal of New Exemption Categories and Processes
- Reducing Regulatory Burden for Minimal Risk Research
- Human Research Subaward Addendum
- Improvement to the Just-in-Time Process



Current Progress

- Practical Guide Sample Pages
- Exemption Wizard Project
- Harmonization Project



Practical Guide for Reducing Regulatory Burden

- Current federal regulations allow considerable [latitude](#) for institutions to determine their own internal policies and procedures for human subjects research.
- The goal of the Practical Guide is to provide a [set of tools](#) that will allow institutions to reduce administrative burdens and maintain superior standards of human subjects protection while adhering to federal regulations.
- The initial topics planned for the Guide are based on recommendations of the [Secretary's Advisory Committee on Human Research Protections \(SACHRP\)](#).
- [Input](#) will be sought (widely) as we continue to develop and improve this resource.



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FDP Contacts

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PRACTICAL GUIDE FOR REDUCING REGULATORY BURDEN

Presented by the FDP Human Subjects Protections Subcommittee

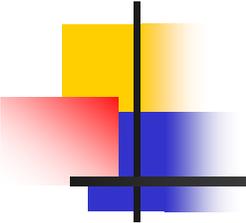
Current federal regulations allow considerable latitude for institutions to determine their own internal policies and procedures for human subjects research.

With this Practical Guide, the committee seeks to provide a set of tools that will allow institutions to reduce administrative burdens and maintain superior standards of human subject protection while adhering to federal regulations. These tools are based on our the member's experiences with successful demonstration projects and those of our forward-thinking colleagues, particularly the Secretary's Advisory Committee on Human Research Protections (SACHRP). We welcome further input from others as we continue to develop and improve this resource.

Some reforms presented in the guide may require institutions to undergo considerable consultation and customization prior to implementation. Other resources, like "Ways to Make Your Study Exempt," are meant to empower individual investigators.

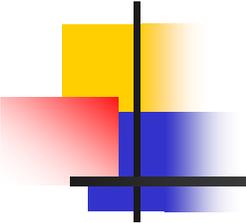
Table of Contents

- 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
- V. Expediting Expedited Review
 - a. Staff as IRB Members or Consultants for Protocol Review
- VI. Customizing Informed Consent to Fit the Study
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- VII. Streamlining Continuing Review
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- VIII. Collaborating with Outside Individuals
 - a. Individual Investigator Agreement (IIA) Template
- IX. Minimal Risk Research



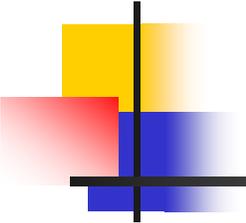
What can SACHRP members do to help?

- Contribute topics for the Practical Guide
- Review and critique project materials
- Clarify guidance
- Share ideas from SACHRP Subcommittees
- Suggest demonstrations for FDP
- Volunteer or suggest individuals for working groups

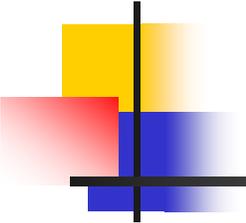


Exemption Project

- Exemption Wizard

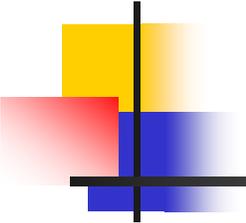


Who Should Review?



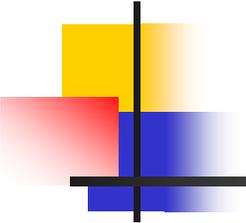
Federal Regulations

- § 46.101 To what does this policy apply?
- (a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.



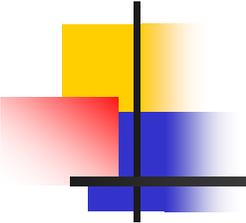
Federal Regulations

- (b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:
- (c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.
- (d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.
- (e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.
- (f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.



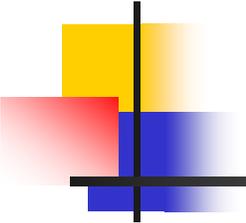
Federal Guidance

- Research activities involving human subjects that are exempt from IRB review are identified in 45CFR 46.101(b)(1)-(6). (Institutions and IRBs may not create new categories of exempt research under 45 CFR Part 46.) Institutions should have a clear policy in place on who shall determine what research is exempt under .46.101(b). **Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions.** In addition, the institution should be prepared to reinforce and review, as necessary, the method of determining what is exempt. OPRR **advises that investigators should not** have the authority to make an independent determination that research involving human subjects is exempt and should be cautioned to check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research.



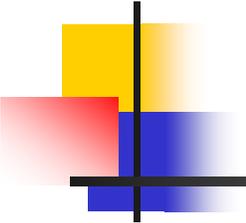
The Exempt Wizard

- Proof of Concept
- Not cast in stone
- Merge into existing smart forms
- Wizard ≠ Watson
- Not mandatory
- Oversight
- Integrity



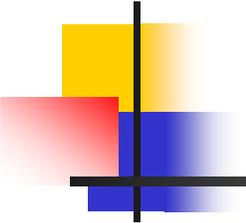
Exemption Wizard

- Electronic
 - Prevents skewing
 - Documentation



Exemption Wizard

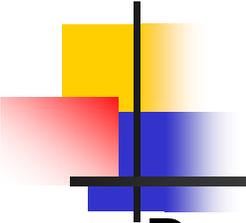
- Demonstration
 - Dual submission, standard application and exempt wizard
 - 20 projects with a determination of exempt
 - 20 projects with a determination of expedited



Harmonization Project

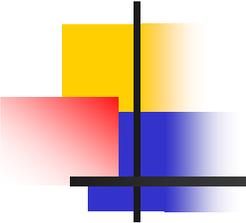
Proposed Project to Outline Agency Policies and Procedures Related to Documenting Compliance with Common Rule

- Federal Agencies that follow the Common Rule may vary in how they implement these regulations and in certification requirements from awardees.
- This may represent an area where increased coordination across agencies could decrease institutional burden without compromising the safety of research participants



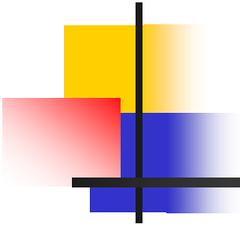
Harmonization Project

- Develop a table of human subjects policies per agency including
 - Agency HS regulations
 - Application Requirements
 - Human subjects section
 - FWA
 - IRB approval
 - Other
 - Awardee Requirements (New and Continuing)
 - Award Terms/Conditions
 - FWA
 - IRB approval
 - Human Subjects Education
 - DSMP/DSMB
 - Clinical Trials.gov
 - Restricted Awards and Terms
 - Other

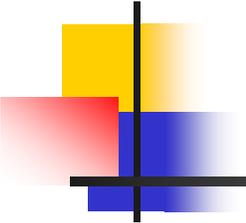


Harmonization Project

- Develop list of Agency contacts (start w/ FDP list)
- Start with NIH and then expand to other agencies
- Identify requirements that have “harmonization” potential
- Explore the possibility of common set of award terms and conditions
- Coordinate w/ Social/Behavioral Sciences Working Group (SBWG) of OSTP’s Human Subjects Research Subcommittee (Common Rule agencies) which is working on a related resource



QUESTIONS?



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