Human Subjects Protections Subcommittee for Reducing Regulatory Burden Update

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

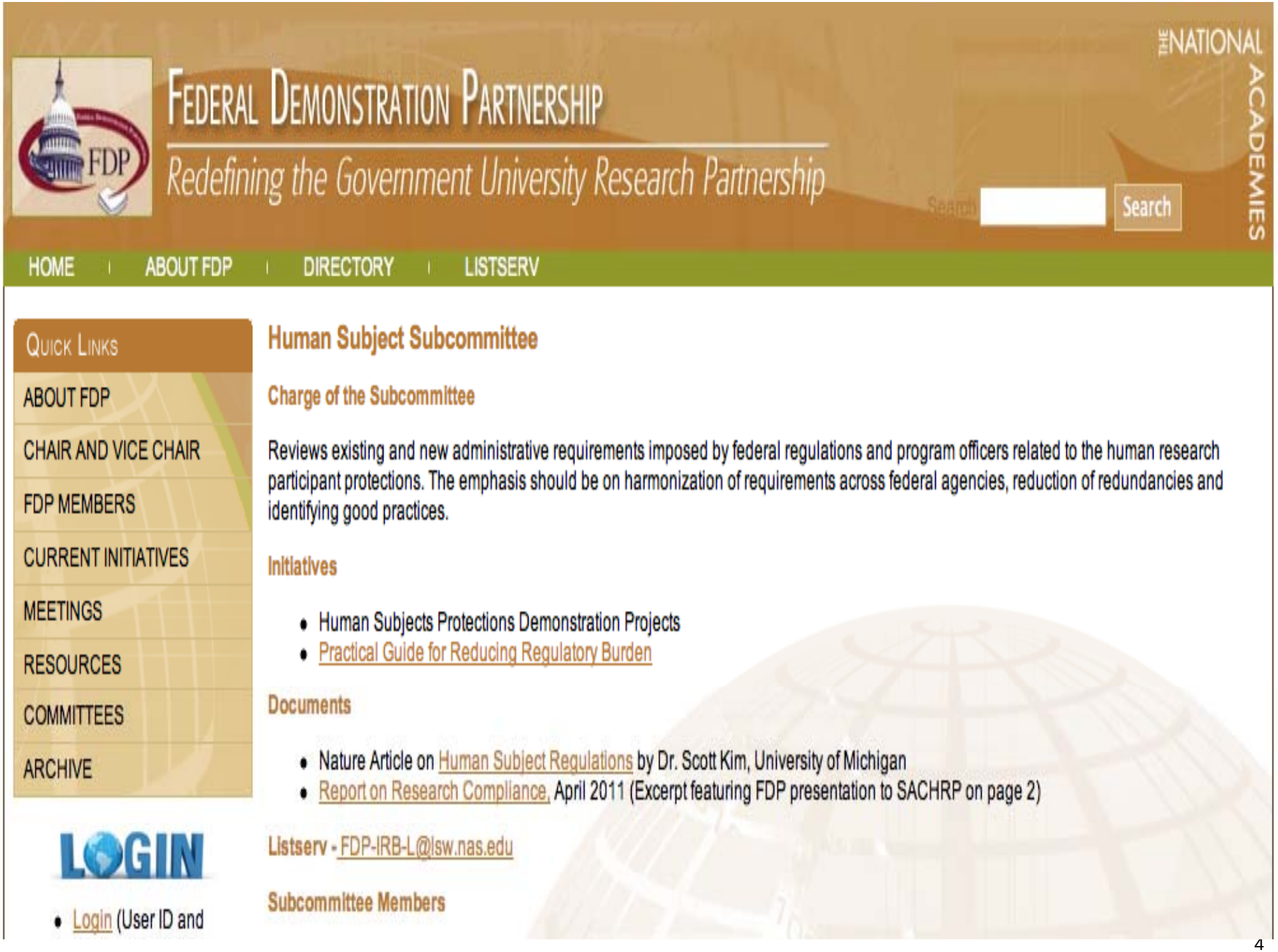
Goals

- 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

- **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**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HOME | ABOUT FDP | DIRECTORY | LISTSERV
QUICK LINKS
ABOUT FDP
CHAIR AND VICE CHAIR
FDP MEMBERS
CURRENT INITIATIVES
MEETINGS
RESOURCES
COMMITTEES
ARCHIVE
LOGIN
Login (User ID and
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

Current Projects

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

Practical Guide for Reducing Regulatory Burden

Work In Progress

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

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- ABOUT FDP
- CHAIR AND VICE CHAIR
- FDP MEMBERS
- CURRENT INITIATIVES
- MEETINGS
- RESOURCES
- COMMITTEES
- ARCHIVE

LOGIN

- Login (User ID and Password required)

PRACTICAL GUIDE FOR REDUCING REGULATORY BURDEN

Presented by the FDP Human Subjects Protections Subcommittee

Table of Contents