



New HRPP Policies and Procedures Manual

An updated Human Research Policies and Procedures Manual is now in effect and posted on the UB HRPP and IRB websites at <http://www.research.buffalo.edu/rsp/>. The document has been reviewed and approved by the Association for the Accreditation of Human Research Protection Programs. The link to the manual is found in the Resources section in the left hand column of the websites. The URL is: <http://www.research.buffalo.edu/forms/hs/ubsop.pdf>

The 180 page manual with glossary describes the procedures, policies and responsibilities pertaining to various aspects of UB's Human Research Protection Program. For your convenience, the Table of Contents has live links from section headings and sub-headings to corresponding sections of the document. The HRPP Policy and Procedures Manual includes the following sections:

1. Introduction
2. Institutional Authority
3. Education and Training
4. The Scope and Authority of the UB IRBs
5. Responsibilities of IRB Chairs, Administrators, Members and Outside Reviewers
6. Functions of the IRB Administrative Office
7. Levels and Types of IRB Review
8. IRB Meetings
9. Criteria for IRB Approval of Research Projects
10. Vulnerable Populations/Groups Requiring Special Consideration
11. Health Insurance Portability and Accountability Act (HIPPA)
12. Research Using FDA Regulated Products: Investigational Drugs, Agents, Biologics and Devices
13. Special Topics
14. The Informed Consent Process
15. Responsibilities of Investigators and Faculty Sponsors
16. Conflict of Interest and Significant Obligations
17. Reportable Events and Problems
18. Non-Compliance with HRPP Requirements
19. Quality Assurance/Quality Improvement Activities

Subsequent issues of *HRPP News Bulletin* will review sections of the manual of greatest interest and value to investigators and research staff including, for example, Section 9. Criteria for IRB Approval of Research Subjects, Section 15. Responsibilities of Investigators and Faculty Sponsors, and Section 16. Conflict of Interest and Significant Obligations.

