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|  JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH | Human Research Protection Program Policies & Procedures | |
| | Identification | Page 1 of 1 |
| Title: Institutional Assurance and Commitments | Date Effective 3/23/04 | Supercedes P&P dated |

Federal and State Regulations

The Federal regulations set the minimum requirements for protection of human subjects who take part in research. The CHR reviews all human subjects research in accordance with the Federal Policy for the Protection of Human Subjects (the Common Rule) and all subparts contained in Title 45 Code of Federal Regulations Part 46 (45 CFR 46 subparts A,B, C & D). In addition, the CHR ensures that all research regulated by the Food and Drug Administration complies with requirements set forth in 21 CFR 50, 21 CFR 56, 21 CFR 312 and 21 CFR 812, and with any additional regulations or policies of relevant agencies, such as the National Institutes of Health or the Department of Education. The CHR also determines whether certain research is exempt from Federal regulations that govern human subjects research. Furthermore, the CHR ensures that all human subjects research conducted in Maryland complies with State and local laws that affect the welfare of research subjects. The CHR will also follow applicable foreign laws that provide additional protections to subjects participating in research when the research is conducted in a foreign country. Additionally, the Office of Research Administration, the Office of Graduate Education and Research and JHU General Counsel contribute to ensuring that CHR policies and procedures are current and that human subjects research activities are compliant not only with human subjects regulations, but with any other laws and regulations that affect the conduct of research at JHSPH.