Improving IRB Efficiency and Protecting Human Research Participants

*Huron’s experts work with clinical research organizations to measurably improve the efficiency of their IRBs, protect research subjects, and achieve accreditation.*

**What Sets Us Apart**
Huron’s Research Services team includes former department administrators, research coordinators, compliance officers, and others who offer an unparalleled mix of expertise, experience, and a reputation for delivering value. Our team works with organizations to efficiently achieve the highest standards of ethical and compliant research.

**A Comprehensive Approach**
Huron provides a comprehensive set of solutions and services for compliant human research protections and Institutional Review Boards (IRBs). These include:

**HRPP Toolkit.** Our comprehensive Human Research Protections Program (HRPP) Toolkit consists of Standard Operating Procedures, worksheets, checklists, templates, process flows, and other business tools for an effective HRPP, and running an IRB.

The policies and procedures in the Toolkit are designed to comply with all federal agencies in the U.S. and ICH-GCP, as well as meet all accreditation requirements. Huron customizes the HRPP Toolkit for your institution to include local regulations and institutional policies.

**Assessment of Current Operations and Policies.** Our team can analyze your existing policies, procedures, and—most importantly—actual practices at clinical research centers, hospitals, and academic medical centers surrounding your HRPP, and advise on how to improve them in terms of compliance, efficiency, investigator, sponsor and staff satisfaction, and cost-effectiveness. We advise on the adequacy of IRBs, the credentials and preparation of IRB staff, and the skills of investigators and research staff.

**Accreditation Support.** Many institutions are now considering accreditation of their human research protections program. Huron can help accelerate the process of achieving accreditation by providing fully-compliant policies and procedures with a proven track record of meeting accreditation requirements, and assisting in training and mentoring your IRB members, staff and clinical investigators.

**Interim Staffing for IRB Offices.** To assist institutions through periods of organizational flux and/or increases in administrative workload, Huron offers interim management and staffing for any component of your human research protection program. Our experienced consultants become a member of your team to help you avoid or manage short- or medium-term backlogs of work.

**Training and Education.** Huron can assist with all aspects of IRB and human research protections-related training for IRB members and staff, investigators, coordinators, administration, and the Institutional Official. Whether this training and education assistance is provided alone or in conjunction with compliance assessments and/or policy and procedure development, we can tailor a program to meet your needs. In virtually any learning environment—one-on-one, large or small classroom setting, workshop, table-top scenario exercises, or web-based—Huron’s professionals can be easily integrated into your learning organization. Learning content is customized to your organization, and can include international and federal requirements, state and local laws, and institutional policies and procedures.
Investigation and Management of Non-Compliance or Misconduct. Huron has the experience to assist with internal investigations, help separate rumor from reality, and provide the guidance necessary to properly manage noncompliance or misconduct consistent with the Department of Health and Human Services, Food and Drug Administration, and Office of Research Integrity requirements. We help our clients communicate with regulatory authorities, providing necessary information while avoiding common mistakes and over-reporting.

Information Technology for Institutional Review Boards (eIRB). Huron has assisted with the development of academic and commercial software for IRBs, and understands the strengths and weaknesses of available systems. We can work with you to take you through the necessary steps to ensure a successful implementation, maximizing the benefits of a streamlined, efficient, transparent, and compliant process.

UNMATCHED EXPERIENCE
Universities, healthcare providers, and medical schools call on Huron’s expertise for the guidance they need to achieve higher standards of efficiency and compliance in their clinical research efforts. Huron has assisted numerous organizations in gaining accreditation and in achieving accelerated IRB approval times while protecting subjects.