HURON'S HRPP TOOLKIT

Huron's HRPP Toolkit represents a complete set of tools including: standard operating procedures, templates, worksheets, checklists and workbooks; designed with the goal of meeting regulatory and accreditation requirements, including:

- Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS)
- Association for the Accreditation of Human Research Protection Programs (AAHRPP)®
- International Council on Harmonization – Good Clinical Practice (ICH-GCP)
- Veterans Administration
- Department of Defense
- Department of Education
- Department of Justice
- Environmental Protection Agency
- Department of Energy

The HRPP Toolkit was designed with the following concepts in mind:

- Maximum regulatory flexibility consistent with compliant procedures
- Easy to follow, non-redundant procedures
- Focus on business process and IRB workflow
- Use of documents to support consistent IRB applications and reviews
- Documents support application of ethical principles.

The Huron HRPP Toolkit documents are organized into the following categories and functions:

- **Standard operating procedures** (SOPs): Describe the actions of individuals including when specific worksheets, forms, checklists, templates and workbooks are to be used; organized by business process (e.g., pre-review, review, post-review) rather than by topic (e.g., continuing review, drugs, and protocol deviations).
- **General documents**: Describe general policy and instruction.
- **Forms**: Describe the information requested by the IRB.
- **Worksheets**: Describe determinations that must be made but do not need to be documented.
- **Checklists**: Describe determinations that must be made and documented.
- **Templates**: Provide templates for minutes, consent documents, protocols and communications.
- **Workbooks**: Provide tables to maintain and track important information.

TOOLKIT IMPLEMENTATION SERVICES	
SERVICES	DESCRIPTION
Toolkit Adaptation	We adapt and deliver an HRPP Toolkit that is customized for your institution after survey completion.
Toolkit Training	A Huron HRPP expert delivers a one-day, on-site walk through of the toolkit, and works with you to develop a plan for future review, updates and an implementation plan.
Ongoing Remote Assistance	During implementation, we provide remote assistance to HRPP leadership while adopting the toolkit.
OPTIONAL TOOLKIT AND HRPP OPERATIONAL SERVICES	
Didactic IRB Member Training	Didactic training covering: • Regulatory criteria for approval • Practical application of the regulatory criteria for approval • Additional considerations required for protection of human subjects • Training on related worksheets and checklists
IRB Meeting Mentoring	Personal mentorship with IRB chairs, vice chairs and staff. Areas of focus include: • IRB meeting prep – review the agenda packet, assist IRB staff with meeting preparation • Conducting IRB meetings – reinforce the focus on the regulatory criteria for approval, ensure minutes documented accurately, exclude unnecessary documentation and can be finalized within 24 hours
Implementation of Investigator-facing Materials	• Investigator-facing materials include: – Investigator manual – Application forms – Protocol and consent templates • We participate in face-to-face meetings with groups of investigators, generally at department, medical staff or other meetings • Adopt an approach that enables you to take over future communications with investigators
Gap Analysis	• Gap analysis of current IRB operations and supporting SOPs, tools, etc. and the HRPP Toolkit. • Assess and highlight areas for change management for the HRPP toolkit implementation.
IRB Organization Evaluation	Review current IRB office and IRB committee organizational structures and make recommendations to maximize resources and increase efficiency.
Mentored Implementation of the IRB Office Procedures and HRPP SOPs	Direct supervision of IRB office operations • Evaluate whether processing and review follow the SOPs and regulations, approve the research according to the least-restrictive regulatory category and apply maximum flexibility available • Conduct mentoring on-site or remotely, as appropriate to the volume and intensity of the work and the needs of your staff.
HRPP TOOLKIT OPTIONAL SUBSCRIPTION SERVICE	
Toolkit subscription service	• Regular toolkit updates to address any regulatory, guidance or accreditation changes and/or feedback and suggestions from HRPP Toolkit clients • Includes release notes outlining toolkit changes, the affected documents and the basis for changes

The Huron Team

Huron's IRB services professionals are uniquely qualified to provide the ideal mix of tools, methodology and experience, a combination that has resulted in a reputation for delivering value. The Huron team includes former IRB directors and managers, AAHRPP site visitors researchers and software professionals.

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