

Human Protocols

Software for IRB Compliance



Human Protocols



Human Protocols, **now powered by Huron's HRPP Toolkit**, provides a complete set of tools (SOPs, templates, worksheets, checklists) designed to meet the regulatory and legal requirements of the 20 federal departments and agencies for human research, and the 2010 version of the AAHRPP Accreditation Standards and Evaluation Instrument for Accreditation. With the HRPP Toolkit, our Human Protocols application sets the standard for achieving and maintaining compliance during clinical trials.

Protocols

- ✓ Build custom human protocol forms.
- ✓ Manage informed consent forms & brochures.
- ✓ Submit, review, and approve protocols online.
- ✓ Copy, amend, and renew protocols.
- ✓ Attach files and links to protocols.
- ✓ Perform text searches across protocols.
- ✓ Track by exemption / expedited categories.
- ✓ Track by vulnerable subjects.



Reviews

- ✓ Manage multiple review assignments.
- ✓ Control review access by role and protocol.
- ✓ Comment on question, section, or protocol.
- ✓ Collaborate online with other reviewers.
- ✓ Compare with previous submissions.

Meetings

- ✓ Schedule agendas for IRB meetings.
- ✓ Draft and finalize meeting minutes online.
- ✓ Add links and attachments to minutes.
- ✓ Check for meeting quorums automatically.
- ✓ Check for reviewer conflicts of interest.

Huron's HRPP Toolkit Integration

- ✓ **SOPs** – Provide comprehensive, succinct, easy to follow practices and workflows.
- ✓ **Forms** – Provide tested and proven templates supporting AAHRPP accreditation.
- ✓ **Checklists & Worksheets** – Simplify the meeting of regulatory requirements while documenting the basis of compliance.
- ✓ **Process Diagrams** – Provide diagrammed workflows of the major business processes to speed implementation.
- ✓ **Investigator Manuals** – Provide specific requirements to maintain investigator compliance.
- ✓ **Human Research Protection Program Plans** – Provide all the policy statements required by the regulations and AAHRPP to facilitate institutional and faculty approval.