Ensuring Human Subject Protection and Compliance — Pandemic-Ready Toolkit

COVID-19 thrust institutional review boards (IRBs) into another dimension of human subject protection. From having to become familiar with seldom-used regulations, to meeting the demand of drastically compressed review timelines, many IRBs struggled to ensure compliance. As COVID-19 testing, treatment and vaccine trials continue, it is key to formalize how the IRB manages them, and other similar occurrences, in the future and ensure quick turnarounds while maintaining compliance.

That is where Huron's IRB services team can help.

Huron's COVID-19 Toolkit

Nationally recognized for providing comprehensive Human Research Protection Program (HRPP) tools to IRBs at universities, health systems and hospitals, Huron culled out guidance specific to the situation created by COVID-19. Developed by compliance professionals with deep expertise, the toolkit contains a complete set of must-have HRPP tools for professionals to meet regulatory and accreditation requirements in a streamlined, efficient manner specifically for research related to the pandemic.

Huron's COVID-19 toolkit offering includes:

- Standard operating procedures
- Regulatory determination tools (including drugs and biologics, devices, emergency use, etc.)
- A COVID-19-specific modification submission form

Additionally, Huron will provide up to 10 hours of consulting time to help you address your institution's specific IRB challenges and make recommendations, in areas such as:

- Business processes and streamlining in the current environment.
- Regulatory issues related to reviewing COVID-19 research.
- Issues related to research on hold due to the pandemic.

Documents in the toolkit are based on current federal regulations, regulatory guidance and Association for the Accreditation of Human Research Protection Programs (AAHRPP) standards, as well as Huron's expertise in best practices for review of drug and device trials related to COVID-19.

Commitment of Support

We'll continue to support you through the pandemic and beyond by providing education, opinions and updated guidance issued by federal agencies on our website.

- Considerations for Evaluating Participation in COVID-19 Human Subjects Research
- COVID-19 HRPP Toolkit Supplemental Documents Release
  - HRPP-Related Federal Guidance on COVID-19
  - Existing Regulatory Pathways and Processes Relevant to COVID-19

To learn more about Huron's expertise, tools and services, contact:
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We'll guide you. You guide your IRB.