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Huron HRPP SOPs: The Complete Package

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"Huron HRPP SOPs" is a complete package for an institutional review board (IRB). In addition to 38 standard operating procedures (SOPs), the package includes a human research protection program (HRPP) plan, 11 forms, 45 templates, 20 worksheets, 16 checklists, five spreadsheet databases, and an investigator manual. The package is designed to meet the requirements of FDA, OHRP and various U.S. governmental departments.

The SOPs are fully featured and concise, as shown by Figure 1 below. They are written around business processes (e.g., pre-review, review, post-review), rather than topics (e.g., continuing review, drugs and protocol deviations). They are based on an IRB process flowchart that alone is well worth the price. They are readily adaptable to electronic IRB systems.

AAHRRP has accepted documents based on the Huron package for human subjects protection accreditation purposes. Huron even provides a free tool for assembling documents into an AAHRPP application. The University of Central Florida, which has a nascent clinical research program, says the Huron package saved 95% of its preparation time. It finds the step-by-step design of the SOPs easy to use. The SOPs follow the regulations closely with "no wiggle room." The Harvard School of Public Health, which has a comprehensive HRPP, found the package user-friendly. A modest amount of customization was required to fit its existing processes.

The package is available free from Huron Consulting Group at http://www.besthrppsops.com.

Figure 1. Example SOP

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SOP: Consultation to the IRB

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-051	1/1/2010	A. Author	B. Approver	1 of 2

1 PURPOSE

1.1 This procedure establishes the process for the IRB to obtain consultants.

1.2 The process begins when the IRB staff or IRB member has identified the need for consultation.

1.3 The process ends when the consultant has provided additional expertise to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IRB invites consultants with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

3.2 Consultants with a Conflicting Interest may not provide information to the IRB.

4 RESPONSIBILITIES

4.1 For review by a convened IRB, IRB staff members carry out these procedures.

4.2 For Non-Committee Review, the Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Identify a consultant with the required expertise who can provide a review. Determine whether the consultant has a Conflicting Interest as defined in "SOP: Definitions." If so, obtain another consultant.

5.2 Contact the consultant and determine availability for review.

5.3 Prepare a packet for the consultant using the "WORKSHEET: Agenda Packet Contents". The information in the packet may be limited to that needed for the consultant to review in order provide the additional expertise needed. If the additional expertise needed does not require review of any materials, no materials need be provided.

5.4 For review by the convened IRB:

5.4.1 Provide the consultant's written comments to the IRB members attending the meeting.

5.4.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.

5.5 For Non-Committee Review:

5.5.1 Directly obtain the information from the consultant.

5.5.2 Document information received orally with the name of the consultant.

6 MATERIALS

6.1 SOP: Definitions

6.2 WORKSHEET: Agenda Packet Contents

7 REFERENCES

7.1 21 CFR §56.107(f)

7.2 45 CFR §46.107(f)

Reviewer

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