Clinical Research Accreditation Standards Published for the Protection of Human Subjects

What happened?

New standards have been published for the accreditation of organizations that conduct research, such as hospitals, universities and academic medical centers, and institutional review boards (IRBs).

What does it mean?

The new accreditation system is intended to improve the protection of human research subjects. The new standards governing sponsor agreements, conflict of interest policies, and informed consent procedures may also be viewed as establishing “best practices” for all organizations involved in the clinical research process, including pharmaceutical companies and medical device manufacturers.

Turn page to find out more about clinical research standards.
The number of active human research studies has skyrocketed in recent years, placing considerable strain on researchers, IRBs and research programs. The introduction to the new Partnership for Human Research Protection, Inc. (PHRP), accreditation system notes the “momentum for more effective protection of human research participants and accountability for organizations conducting research has intensified over the past several years as news reports of research related tragedies have become more common . . .”

There have been a number of federal regulatory initiatives for the protection of human research subjects over the past 30 years.

The most recent standards were published by the National Committee for Quality Assurance (NCQA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the nation’s two largest health care accrediting organizations, through the auspices of the PHRP, a newly created, private, non-profit organization. The newly published PHRP accreditation standards are derived largely from the Common Rule and FDA regulations, but they are intended to apply to all research, regardless of funding source.

PHRP offers two accreditation programs: one for organizations that conduct human research and one for institutional review boards. By accrediting an organization, PHRP attests that the organization has (1) implemented a systematic approach to protecting human research subjects, appropriate to the nature of research conducted or reviewed, and (2) established a system to review and improve the protections. The standards for PHRP accreditation are organized into the following four categories:

- **Organization responsibilities** – includes requirements for education, training, and quality improvement
- **IRB Structure and Operation** – includes requirements for IRB organization and composition, and investigator responsibilities
- **Consideration of Risks and Benefits** – includes requirements relating to balancing risks and benefits of research
- **Informed Consent** – includes requirements for obtaining and documenting informed consent

Organizations are required to submit their data for the accreditation survey using a Web-based survey system. The first PHRP survey may result in accreditation for either one year (which necessitates a re-survey the following year), or three years. If the first survey indicates that accreditation would be denied, organizations are permitted to postpone the decision without penalty and request a follow-up survey within one year after receiving the results of their first survey. Further information about PHRP and the accreditation program are available on its website, www.phrp.org.

The standards include requirements for sponsor agreements, conflict of interest policies, and informed consent procedures. Since the PHRP, in developing the standards, consulted with many industry leaders and scientific experts, these standards may come to be viewed as “best practices,” not just for organizations that conduct human research, but also for the sponsors of that research. Attached are lists of these requirements.

This W•H•I•M™ and the attached Quick Reference Guide were prepared by David S. Antzis, Esquire who is a member of the Saul/Life Strategic Alliances subgroup, and is Chair of the Firm’s Business Department. David can be reached at dantzis@saul.com or (610) 251-5055.

The following are certain of the PHRP standards to be used in evaluating the accreditation applications of organizations that conduct human research and IRBs. We believe that these new standards may quickly be viewed as establishing “best practices” for all life sciences companies involved in the clinical research process.

Sponsor Agreements

- Using quality assurance and control systems to ensure that studies are generated and documented in compliance with the protocol and applicable regulatory requirements.
- Subjecting protocol design to peer review.
- Using research teams that are appropriately trained and qualified to conduct the research.
- Prohibiting recruitment incentives or bonuses that might exert undue influence.
- Reporting of adverse events resulting from the research.
- Protecting the integrity of the research by allowing publication of all results, whether positive or negative, based on the scientific judgment of the researchers.
- Refraining from seeking consent or authorization for unlimited or unspecified future uses of research data and/or specimens.
- Using identifiable subject data generated during the research for the sponsor’s analysis and understanding of the study and the product being studied and to interact with regulatory authorities.
- Protecting the privacy of subject data collected during the research.

Conflict of Interest Policy

- Defining what constitutes a significant interest (both financial and nonfinancial).
- Establishing how covered individuals will report significant interest.
- Establishing the process for determining when a particular significant interest is a conflict of interest.
- Providing for protection of privacy of individuals’ financial information except as needed to manage conflict of interest.
- Providing for inclusion of research participants or individuals not affiliated with the organization in determining conflict of interest.
- Distinguishing the respective spheres of authority of a conflict of interest process and the IRB.
- Identifying who has the authority to impose measures to manage conflict of interest.
- Establishing how information concerning conflict of interest will be reported to the IRB.
- Establishing how conflict of interest in human subject research will be disclosed to research subjects, the public and others.
- Describing how violations of the policy will be addressed.

Informed Consent Procedures

Organization’s Instructions to Investigators for the Process of Informed Consent

- State that the IRB has the authority to observe the consent process.
- State when the assessment of the subject’s capacity to consent to a research protocol is required.
- Identify who, under state and local law, may serve as a legally authorized representative for a

(Continued ...)

Saul/Life

Regulatory, Data & Privacy Management
Bruce D. Armon – Team Leader

Litigation & Risk Management
William M. Janssen – Team Leader

Medical Devices
John B. Reiss – Team Leader

Strategic Alliances
Francis V. McNamara, III – Team Leader

Baltimore | Chesterbrook | Harrisburg | Philadelphia | Princeton | Washington, DC | Wilmington
subject determined to be incapable of making an autonomous decision.

- Identify who is eligible to inform the prospective subject about all aspects of the trial and conduct the informed consent process.
- State that investigators must obtain consent prior to entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB.
- Require that information be given to the subject, or the subject’s legally authorized representative, in a language that is understandable to the subject or representative.
- Require that the prospective subject or the legally authorized representative be given sufficient opportunity to consider whether or not to participate, without coercion or undue influence.
- State that consent is an ongoing process.

**Organization’s Instructions to Investigators on Informed Consent Forms**

- That the informed consent form must be approved by the IRB and signed by the subject or the subject’s legally authorized representative, except in cases where the documentation of informed consent is waived by the IRB.
- That the consent form includes all basic elements of information, as set forth in federal regulations.
- That the consent form includes appropriate additional elements of information, as set forth in federal regulations.
- That the consent form includes information concerning payment to subjects, including the amount and schedule of payments.
- That the consent form contains information in language understandable to the subject or to the legally authorized representative.
- That no informed consent, whether oral or written, may include any exculpatory language through which the subject or the legally authorized representative is made to waive or to appear to waive any of the subject’s legal rights, or to release or to appear to release the investigator, the sponsor, the organization or its agents from liability for negligence.
- That the content of consent forms must be consistent with state laws regarding content.

**Each Informed Consent Form Should Contain the Following Elements of Information**

- A statement that the study involves research.
- An explanation of the purposes of the research.
- The expected duration of the subject’s participation.
- A description of the procedures to be followed.
- Identification of any experimental procedures.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others that may reasonably be expected from research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- A statement that the FDA may inspect the records.
- For research involving more than minimal risk, an explanation as to whether any compensation exists if injury occurs.
- For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs, and if so, what the treatments consist of or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about research.

(Continued ...)

---

**Saul/Life**

<table>
<thead>
<tr>
<th>Regulatory, Data &amp; Privacy Management</th>
<th>Litigation &amp; Risk Management</th>
<th>Medical Devices</th>
<th>Strategic Alliances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruce D. Armon – Team Leader</td>
<td>William M. Jansen – Team Leader</td>
<td>John B. Reiss – Team Leader</td>
<td>Francis V. McNamara, III – Team Leader</td>
</tr>
</tbody>
</table>

Baltimore | Chesterbrook | Harrisburg | Philadelphia | Princeton | Washington, DC | Wilmington
• An explanation of whom to contact for answers to pertinent questions about research subjects’ rights.
• An explanation of whom to contact in the event of a research-related injury to the subject.
• A statement that participation is voluntary.
• A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
• A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**Informed Consent Forms Should Also Include the Following Information When Applicable**

• A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
• Anticipated circumstances under which the subject’s participation may be terminated by the investigator without the subject’s consent.
• Any additional costs to the subject that may result from participation in the research.
• The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.
• A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.
• The approximate number of subjects involved in the study.

*This WHAM and Quick Reference Guide was prepared by David S. Antzis, Esquire who is a member of the Saul/Life Strategic Alliances subgroup, and is Chair of the Firm’s Business Department. David can be reached at dantzis@saul.com or (610) 251-5055.*