



Research Quarterly

News for and by the IRB and Research Professionals of St. John Healthcare System

**Welcome to the First Edition of
the Research Quarterly!**

by
Peter A. Nickles, M.D.
Chairman, Institutional Review Board

The St. John Hospital & Medical Center Institutional Review Board (IRB) feels that the distribution of information to research professionals is important, and imperative to good clinical practice (GCP), and effective research within our organization. It is for this purpose that the IRB has created the Research Quarterly Newsletter. This newsletter will be published in May, July, October, and January of each year to further the education and knowledge base of IRB professionals, primary Investigators, research coordinators, and other research personnel.

The IRB would like to invite all researchers, investigators, coordinators, and other research personnel to submit ideas, articles, research tidbits, and updates to Mary Barnhart, the IRB Coordinator, IRB Programs by fax at 313-343-7840 or through email at mary.barnhart@stjohn.org. This is a newsletter by and for research professionals. If you have an area of interest, exciting study developments, need for specific research, or research updates, please feel free to submit them for publication. We hope this publication will provide you with information that will assist you in the research process and help make

the St. John Healthcare System IRB a trendsetter in the research community.



IRB NEWS

By
Peter A. Nickles, M.D.
Chairman, IRB

COMPUTER BASED RESEARCH TRAINING REQUIRED PRIOR TO PROTOCOL APPROVAL

The Institutional Review Board of St. John Hospital & Medical Center (SJHMC) requires that all key personnel participating in human subjects research complete educational training in the protection of human research subjects. All investigators, co-investigators and study coordinators are considered key personnel. Others may also be included.

This initial requirement may be fulfilled by one of the following:

- 1) completion of the computer based training <http://ohsr.od.nih.gov/cbt> IRB

Members section, **OR**

2) completion of the computer based training at <http://cme.nci.nih.gov>

All IRB members and staff must complete the IRB Members section in (1) above.

Option (2) provides up to 2 hours of category 1 credit (accredited by the Accreditation Council for Continuing Medical Education, ACCME)

DOCUMENTATION

A copy of the "Certification of Completion" at the end of each program **must** be sent to the IRB Office, Medical Education, St. John Hospital and Medical Center, for documentation.

Why is Training Necessary?

The purpose is to assure that all research investigators have had appropriate institutional training before conducting human subject research. The goals for education are (1) increase knowledge of, and sensitivity to, issues surrounding the responsible conduct of research (2) improve the ability of participants to make ethical and legal choices in the face of conflicts involving scientific research (3) develop appreciation for the range of accepted scientific practices for conducting research (4) provide information about the regulations, policies, statutes, and guidelines that govern the conduct of research (5) develop positive attitudes toward life-long learning in matters involving the responsible conduct of research. The certificate is printable after completion of the training and can be submitted with your application. Documentation of completion will be kept in file in the IRB Office.

REMEMBER! NO PROTOCOLS WILL BE APPROVED BY THE IRB WITHOUT EVIDENCE OF RESEARCH ETHICS TRAINING.

IRB UPDATE
by

IRB Administrative Office



Jan Pinchak, IRB Coordinator Retires

St. John Hospital and Medical Center and the IRB would like to extend to Jan Pinchak, the former IRB Coordinator our thanks and best wishes as she retires from our facility.

Jan has done an exemplary job in management of the IRB and providing resources and education to our staff over the past years. She will be missed.

Congratulations and well done!



St. John Hospital & Medical Center and the IRB would like to welcome Mary Barnhart, MA, CIM, CIP, as she joins our staff as the new IRB Coordinator. Mary comes to us from Oakwood Healthcare System with seven years of IRB Experience as well as a Master's in Bioethics.

For research and application materials, or IRB information, Mary can be contacted at 313-343-8314 or through email at mary.barnhart@stjohn.org, by fax at 313-343-7840.

New Application Forms

The IRB application has been revised. Please contact our office you need the new version. The consent form skeleton has also been updated. We will be happy to provide copies. We also want to encourage electronic submission of application materials. A signed copy of the application form still needs to reach us in a timely fashion.

WE ARE MOVING!

As of May 5, 2005, the IRB Office is moving. We will be located on the third floor of the MACK Office Building address:
19251 Mack Ave, Suite 340, Grosse Pointe Woods, MI. 48238

Telephone and Fax numbers will remain the same. **No business will be conducted on May 6 or May 9th, 2005, as the office is being physically transferred and restored.**

IRB INFORMATION CORNER



The following is a protocol submission checklist to facilitate full and accurate submission of all protocols to the Institutional Review Board (IRB). The checklists outline some valuable questions the researcher should ask when planning and submitting a protocol for approval.

PROTOCOL SUBMISSION CHECKLIST

Procedure

In conducting the initial standard or full board review of proposed research, the IRB must obtain information in sufficient detail to make determinations required under Federal Regulations, as described in Policy 1, Jurisdiction, Authority and Responsibilities of the IRB (See Standard Operating Procedures).

Materials To Be Provided to the IRB

Copies of the following documents are to be provided to the IRB Office at least two (2) weeks before the next scheduled meeting.

- A completed IRB application with a signed signature page (Please make sure all appropriate signatures are obtained)
- A completed protocol (four copies)

- Proposed informed consent document(s) and/or script as appropriate
- Copies of relevant surveys, questionnaires, data gathering tools or videotapes that will be used in the research project.
- Investigator's Brochure, Device Manual, or Package Insert and/or a document that specifies safety experience
- Subject recruitment procedures and materials (e.g. advertising, fliers, e-mail, commercial scripts, etc.)
- Budget Information, financial forms (Also New)
- Any other documents that the IRB may require to fulfill its responsibilities
- Research Ethics Training Verification

DO YOU KNOW THE ELEMENTS OF INFORMED CONSENT ?

INFORMED CONSENT CHECKLIST

When using humans as subjects in research you must obtain their informed consent. Check each of the following items as they appear in your Informed Consent Document and include this checklist with your protocol:

- A statement explaining the purpose of the research
- A statement of the expected duration of the subject's participation.
- A description of the procedures to be followed.
- A description of any reasonable foreseeable risks or discomforts to the subject, including invasion of privacy.
- A description of any benefits resulting from the research, either to the subject or to others.
- A statement that informs subject of his/her right not to be a subject in a research project.
- A statement informing the subject about how his/her confidentiality will be protected (by assigned code numbers, by limitations of who has

access to data, by data storage in locked cabinets, by locked computer files, etc.)

- A statement that the subject's participation is voluntary, and that his/her refusal to participate will involve no penalty or loss of benefit to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- A disclaimer (if applicable) regarding the use of the Internet to collect data.
- For research involving more than minimal risk, an explanation regarding the availability of any compensation or any medical treatments if injury occurs.
- If written informed consent is required, a place for the subject to sign and date the form and a statement that a copy of the signed consent form will be given to the subject for his/her records.
- If the subject is a minor, a statement of parental responsibility in consenting to the child's participation in the study with a place for the parent to sign and date form, in addition to the participant's signature.
- The name, and contact numbers of the principal investigator and staff.
- A statement informing subject that inquiries regarding the nature of the research, his/her rights as a subject or any other aspect of the research can be directed to the IRB Coordinator.

DOES YOUR INFORMED CONSENT CONTAIN ALL THE NECESSARY ELEMENTS???????????

Research: A Shared Responsibility

St. John Hospital & Medical Center (SJHMC), investigators, research staff, the IRB Office, and the IRB share collective

responsibility for the ethical conduct of human subjects research. To be effective, this collaborative responsibility requires a culture of trust, openness, and honesty. SJHMC must uphold the highest ethical principles in the conduct of research. By upholding the highest standards in a safe research environment, SJHMC can build public support for the pursuit of greater knowledge.

The dignity and welfare of individuals who participate in research is a central concern in the protection of human subjects. Our primary goal must be to assure the development of a fair and explicit process in which subjects voluntarily decide to participate in a study based on an intelligent and knowledgeable assessment of the risks and benefits of the research.

Review of human subjects research performed by employees, participating guests, students, or contractors of SJHMC is required. The institution and the IRB conduct this review. The composition of the IRB is mandated by the federal regulations, and requires scientific and nonscientific individuals from various directorates at SJHMC, as well as community representatives who are not affiliated with the institution.

The IRB is charged with a twofold mission to (1) determine and certify that all projects reviewed by the IRB conform to the regulations and policies set forth by the Department of Health and Human Services (DHHS) regarding the health, welfare, safety, rights, and privileges of human subjects and (2) assist investigators in conducting ethical research that complies with the DHHS regulations in a way that permits the success of the research activity.

The mission is accomplished through IRB review of protocols, discussion between investigators and the IRB during the review process, and IRB/IRB Office outreach to the research community. The process serves to ensure the safe and ethical conduct of human research and the protection of the rights and welfare of subjects.



What is significant or non-significant risk of devices?

Significant Risk (SR) Device:

A significant risk device is an investigational device that: (1) is intended for implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; (4) otherwise presents a potential for serious risk to a subject.

The risk determination should be based on the proposed use of a device in an investigation, and not on the device alone. In deciding if a study poses a SR, an IRB must consider the nature of the harm that may result from use of the device. Studies where the potential harm to subjects could be life threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure should be considered SR. Also, if the subject must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the IRB must consider the potential harm that could be caused by the procedure in addition to the potential harm caused by the device. Two examples follow:

- The study of a pacemaker that is a modification of a commercially - available pacemaker poses a SR because the use of any pacemaker presents a potential for serious harm to the subjects. This is true even though the modified pacemaker may pose less risk, or only slightly greater risk, in

comparison to the commercially - available model. The amount of

potentially reduced or increased risk associated with the investigational pacemaker should only be considered (in relation to possible decreased or increased benefits) when assessing whether the study can be approved.

- The study of an extended wear contact lens is considered SR because wearing the lens continuously overnight while sleeping presents a potential for injuries not normally seen with daily wear lenses, which are considered NSR.

Non-Significant Risk (NSR) Device:

Non-significant risk devices are devices that do not pose a significant risk to human subjects. Examples include most daily-wear contact lenses and lens solutions, ultrasonic dental scalers, and foley catheters.

Both significant and non-significant risk device studies require IRB approval prior to initiation of clinical study. If the IRB disagrees with the sponsor and/or primary investigator that the device poses an NSR, the sponsor is then required to report this finding to the FDA within five (5) working days (CFR 812.150(b)(9)). The sponsor must obtain and maintain IRB approval throughout the investigation as an NSR device study.

What is study "risk"?

Risks, harms, inconveniences, discomforts, whether they are physical or psychological in nature, may come about as a result of activities performed in research projects. These occurrences should be reduced as much as possible when utilizing human participants. The type of IRB approval, of course, depends upon the level of minimal risk, where it is defined as "where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [\[45 CFR 46.102\(i\)\]](#)

In general, the higher the risk involved in the project, the more detailed the explanation, precautions, and informed consent must be. Below are general guidelines indicating the degrees of risk that may be of assistance.

High Risk: Activities in medical or behavioral science research that may induce a potentially harmful altered physical or mental state or condition are forms of personal invasion and, as such, are considered to be in a "high risk" category. Examples include biopsy procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exercise; hypnotism; and subjection to deceit, public embarrassment and humiliation. In these cases there must be especially careful documentation to show that the benefits outweigh the risks.

Intermediate Risk: Activities involving a wide range of medical, social, and behavioral projects, in which there is no immediate physical risk to the subject, are considered to be in an "intermediate risk" category. Examples include personality inventories; interviews; questionnaires; the dissemination of any data or information concerning an identified individual; information gathering activities conducted in classrooms or elsewhere; individual or group therapy sessions; or the use of photographs, taped records, and stored data. Since some of these of procedures may impose a varying degree of demeaning or dehumanizing conditions, prior written informed consent is required. However, since this type of activity does not involve physical invasion but is where voluntary consent on the part of the subject is desirable, a more simplified consent is acceptable.

Low Risk: Certain activities are classified as "low risk" and may not require a written informed consent. An example is the use of completely anonymous questionnaires. If a written informed consent is deemed unnecessary or undesirable in a particular instance a waiver of written consent may be requested. Low risk involves situations in

which there is no conceivable physical or mental discomfort, and the measurements made on subjects can be considered to be reasonably unobtrusive. In these situations written informed consent may be waived.

Suggestions or Comments on this Newsletter



If you have any suggestions or comments regarding this newsletter, its design or content, please contact, Mary Barnhart, at our IRB Office 313-343-8314.

If you would like to contribute to this newsletter and/or have suggestions for articles and information you would like included please let us know.

The purpose of this publication is to inform, educate, and provide a forum for discussion of research related issues.

The IRB hopes that the information provided in this newsletter has given you insight and provided you with valuable information.

IRB Office Information:

Hours of Operation:

Monday through Friday, 7:30 AM – 4:30 PM

Contact Information:

Telephone Number: (313-343-8314)
Fax Number: (313)-343-7840