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# IRB consortia as an approach to facilitating effective and efficient reviews

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# IRB CONSORTIA AS AN APPROACH TO FACILITATING EFFECTIVE AND EFFICIENT REVIEWS

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# A LOOK AT THE ST. LOUIS IRB CONSORTIUM

- Founded in May 2002

- Mission: to provide a forum where local IRB staff and members can meet to
  - share ideas and educational opportunities;
  - discuss regulations and ethics governing research;
  - assist each other with problem solving.

# MEMBERSHIP

- Open to all local IRBs their staffs, and committee members.
- Member institutions may be asked to host Consortium meetings or events.
- Members are asked to support the efforts of the Consortium.
- Currently, there is no membership fee

# HOW IT IS RUN – ITS NUCLEUS

- The nucleus institution, currently WU, is responsible for
  - setting meeting dates, times, and locations;
  - preparing the agenda for meetings;
  - preparing meeting minutes;
  - notifying member institutions of information sent to the Consortium;
  - managing the budget; and
  - ensuring the cohesion of the organization.

# MEMBER ORGANIZATIONS

- Appoint a Point Person who serves as the **primary contact** person for that member institution.
  - **responsible for information flow** to and from the Consortium
  - **notifying members** at their institution of Consortium activities.
  - assist the nucleus organization in **identifying topics and presenters** for meetings and events.

# SAMPLE AGENDA TOPICS

- Wards of the State in research studies
- A Paradigm for Review
  - based on Emanuel's article "What Makes Research Ethical"
- Internet Research Guideline
- Patient Advocacy
- Unanticipated Problem Guideline
- Regulatory Monitoring – from the prospective of the Clinical Research Coordinator; how CRCs prepare for audits

# HOW THIS HELPS FACILITATE REVIEWS

1. All area IRB staff get to know one another.
   - Networking amongst ourselves for best practices,
     - e.g. how do you handle nutritional supplements, do you require human subjects education for compassionate use studies, etc.

2. Guidelines, forms, and procedures developed at one institution are often adopted at other Consortium institutions. Examples include:
   - Wards of the State
   - Data Monitoring (WU and SLU)
   - IRB Full Board application form (WU and SLU)

# SHARE EDUCATIONAL RESOURCES

- Together Consortium members develop educational programming
  - First, agree on topics of importance
  - Second, agree on the speakers and message
  - Third, deliver a common message across institutions

# SAMPLE AGENDA LOCAL CONFERENCE

*Necessary Elements for the Enhancement of the Responsible Conduct of Research, June 2004*

List of Speakers:

Mark S. Wrighton, PhD, Chancellor
Larry Shapiro, MD, Executive Vice Chancellor and Dean
Philip Ludbrook, MD, Associate Dean and Executive Chair, IRB
Washington University in St. Louis

Kenneth I. Shine, MD, Executive Vice Chancellor for Health Affairs, University of Texas System

Bernard Schwetz, DVM, PhD, Director, Office for Human Research Protections

# A NATIONAL HUMAN SUBJECTS PROTECTION CONFERENCE
## *"FROM THE PAST TO THE FUTURE: EVOLVING RESEARCH ISSUES"*

2004 Keynotes:

Genetics; Health Care Policy ; Medicine and Research: The Holocaust;
The Nuremberg Trials

2004 Breakout topics

Washington / Federal Updates; International Research; Genetic testing and it's impact;

Web-based Research; Collaborative Research; Investigational and Humanitarian Devices

Inconsistency of IRB Review; Minorities in Research; Social & Behavioral Research

Prisoners in Research; Handling Non-Compliance; Cognitively Impaired

Ethical Discussions; Consent Issues; Electronic Submission; Pharmocogenetics

# WORK ON COLLABORATIVE PROJECTS

- NIH Grant applications to improve IRB reviews
- ARENA grants to bring speakers to the Consortium
- Networking with local regulatory officials such as FDA

# REFERENCE SLIDES

# CHARTER

## INTRODUCTION

In Fall 2001, representatives from Washington University School of Medicine Human Studies Committee traveled to Kansas City, Missouri to visit the IRB Consortium started by the Midwest Bioethics Center. St. John's Mercy Medical Center, the Veterans' Administration, and Saint Louis University were approached with the idea of starting a consortium in St. Louis. The idea was well received and the St. Louis IRB Consortium was established.

## MISSION

The purpose of the St. Louis IRB Consortium is to provide a forum where local IRB staff and members can meet to share ideas and educational opportunities; discuss regulations and ethics governing research; assist each other with problem solving.

## ORGANIZATION

Currently, Washington University School of Medicine's Human Studies Committee is serving as the nucleus of the Consortium. The nucleus institution is responsible for setting meeting dates, times, and locations; preparing the agenda for meetings; preparing meeting minutes; notifying member institutions of information sent to the Consortium; managing the budget; and ensuring the cohesion of the organization.

All members appoint a point person who serves as the primary contact person for that member institution. The point person is responsible for information flow to and from the Consortium as well as notifying members at their institution of Consortium activities. Point people also assist the nucleus organization in identifying topics and presenters for meetings and events.

## MEMBERSHIP

Membership is open to all local IRBs their staffs and committee members. Member institutions may be asked to host Consortium meetings or events. Members are asked to support the efforts of the Consortium. Currently, there is no membership fee but this may be instituted in the future.

## RESOURCES

The St. Louis IRB Consortium was started with funding provided by Washington University, the Veterans' Administration, St. John's Mercy Medical Center, and Saint Louis University. As a result, funds are limited and an institutional membership fee may be instituted in the future to cover costs of meetings and events.

# SAMPLE AGENDA

IRB CONSORTIUM MEETING
FRIDAY, January 25, 2008
11:00 am – 1:00 pm

Location: Brazie's Restaurant on the Hill,
3453 Hampton, St. Louis, MO 63110, 314-481-5464

**NOTE:** The new meeting time and location for this meeting were discussed at the last IRB Consortium meeting. Future plans for the Consortium will be discussed at the January 25, 2008 meeting.

St. Louis IRB Consortium

revisiting the Charter, conduct of the meetings, locations and times
updating the Consortium lists and point people for each institution

Information Sharing

a. St. Luke's "Subject Recruiting: The Missing Links" educational program
i. Wednesday, Jan. 30, 2008
ii. Registration requested by Friday, Jan. 25, 2008

b. 2008 Office of Research Integrity Conference at Washington University
i. Thursday, April 17 to Saturday, April 19
ii. Contact Cathy Striley, PhD at 314 286-2268 or strileyc@wustl.edu for more information.

c. Any other news

# SAMPLE MINUTES

**In attendance were representatives from:** SLU, Washington University, Komen Research Advocacy Committee, Missouri Baptist, Barnes-Jewish, St. John's and St. Luke's Hospitals (total # - 15 people)

**Future Meetings**

Meetings are held the fourth Tuesday of the month, every three months, at 4:00 pm unless otherwise noted.

**Keynote Presentation: Judy Johnson, MBA; Rachel Dorris; and Helen Chesnut – "Patient Advocacy".**

Ms. Johnson discussed her experience with Komen St. Louis and her role in breast cancer research, while Ms. Dorris and Ms. Chesnut discussed their experiences with the disease and views of consenting research participants.

*Judy Johnson, MBA will be heading up the talk on patient advocacy. Judy is a Sr. Clinical Research Associate in Radiation Oncology at the Siteman Cancer Center who is very involved with Komen. She will share a little bit about what Komen St. Louis Affiliate is doing regarding breast cancer research advocacy, and about how she got involved.*

*Rachel Dorris. Ms. Dorris is a 3 year beast cancer survivor, diagnosed at age 32. She does volunteer breast cancer advocacy work. She, too, is employed at WU working as a clinical research associate.*

*Helen Chesnut has been involved with Komen for more than 7 years. Helen not only is a breast cancer survivor herself who participated in a clinical trial, but has had dear friends battle this disease as well. Helen is currently serving as the manager of Fund Development at Komen St. Louis Affiliate, but she has held many other roles as a volunteer, including chairing the Komen St. Louis Race for the Cure.*