

Regulatory Issues with Human Subjects Research

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Objectives

- Recognize the research activities that need to be submitted to the IRB
- Explain the process for IRB submissions
- Review the information required for new IRB submissions
- Explain why registering your trial on clinicaltrials.gov is important

Research Definition

- “...a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.”

Examples of Research

- Retrospective evaluations (chart reviews)
- Surveys (anonymous or identifiable)
- Case-control studies
- Prospective randomized trials

Basically, if you are collecting data of any kind it may be research.

Not research, but reviewed by the IRB

■ Case reports and case series

- Required because the IRB at Temple is also the HIPAA compliance office for research-related activities.

■ Humanitarian use devices

- These are FDA-approved devices where initial IRB review and continuing review is required by regulation.

IRB Submissions

- What you need:
 - IRB training (human subjects training)
 - Study information
 - Description of what the study entails
- New submission forms are being adopted
 - Should be available online in early February and will be required for submissions after March 1, 2012
- Remember: all communications from the IRB occur through the University email system



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Investigator Manual

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Why Register Your Study With the IRB?

- It's a University requirement that all research be reviewed before the study starts.
- Failure to submit research, or changes in research can result in the inability to participate in other studies, personal or professional embarrassment.
- Journals are requiring documentation of IRB review and approval of studies.

Registering with clinicaltrials.gov

- Contact Stephanie Bricton at the Temple University Office of Clinical Trials
 - Phone: 215-707-9190
 - Email: brictson@temple.edu

Why Register Your Study With clinicaltrials.gov?

- Provides a site where individuals can describe the study BEFORE the data is collected.
- Changes in research methodology are also tracked.
- Serves as a recruitment tool
- Also required by many journals prior to publication

Gastrointestinal Toxicity With Celecoxib vs Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis

The CLASS Study: A Randomized Controlled Trial

JAMA, September 13, 2000—Vol 284, No. 10

Interventions Patients were randomly assigned to receive celecoxib, 400 mg twice per day (2 and 4 times the maximum RA and OA dosages, respectively; n=3987); ibuprofen, 800 mg 3 times per day (n=1985); or diclofenac, 75 mg twice per day (n=1996). Aspirin use for cardiovascular prophylaxis (≤ 325 mg/d) was permitted.

At the end of six months the study showed:

Conclusions In this study, celecoxib, at dosages greater than those indicated clinically, was associated with a lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically important toxic effects, compared with NSAIDs at standard dosages. The decrease in upper GI toxicity was strongest among patients not taking aspirin concomitantly.

12-month study data submitted to the
FDA revealed no statistically
significant differences in symptomatic
ulcers or ulcer complications.

Questions?

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