

**Research: Bridging the Gap from Clinic to ASC
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Objectives:

- State history of clinical research standards
- Identify the roles of the Ophthalmic Clinical Research Coordinator & the Ambulatory Surgery Staff
- Discuss the importance of good communication between Research Coordinator & ASC for adherence of Research Protocols

Ophthalmic Clinical Research Coordinators (CRC) and Ambulatory Surgery Center staff (ASC) should understand the history of clinical research trials, current rules and regulations that govern all clinical trials, and the infancy of drug development. This information broadens the ambulatory surgery staff knowledge of Good Clinical Practice (GCP) - the international ethical and quality standard for clinical trials with human subjects.

Throughout this presentation we will explore how two different clinical areas can accomplish the research goals with good communication, staff education & appropriate delegation of responsibilities.

Historical/Infamous Clinical Trial

U.S. Public Health Service Syphilis Study at Tuskegee Institute, Tuskegee, Alabama “Tuskegee Study of Untreated Syphilis in the Negro Male”

- 1932 Tuskegee Study begins
- Purpose intended to record the natural history of syphilis in hopes of justifying treatment program for blacks
- Initial subject population 600 black men – 399 with syphilis, 201 without syphilis
- No Informed Consent
- The true purpose of this study was never revealed to the subjects
- Subjects did not receive proper treatment for a cure. Penicillin accepted as treatment of choice for syphilis in 1945
- Subjects received free medical exams, free meals, and burial insurance for study participation

- Study proposed to last for 6 months, lasted for 40 years
- Study was deemed “ethically unjustified” in 1972

References:

Center for Disease Control & Prevention. Tuskegee.

www.cdc.gov/tuskegee/timeline.htm

Regulatory and Ethical Codes

- Within the Department of Health and Human Services (HHS) HHS Regulation 45
- CFR part 46 at the Office for Human Research Protections HHS Guidance at the Office for Human Research Protections Regulation and guidance at the Food and Drug Administration’s Good Clinical Practice portal
- The Belmont Report - Written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Outside Department of Health and Human Services (HHS)

- Association for the Accreditation of Human Research Protection Programs
- Council for International Organizations of Medical Sciences (CIOMS), including International Ethical Guidelines for Biomedical Research Involving Human Subjects
- Declaration of Helsinki - International doctrine, written in 1964 by the World Medical Organization and revised several times since then. The Declaration defines basic tenets of human rights in biomedical research involving human subjects.
- Nuremberg Code - The ethical guideline written as a result of World War II Nazi war crimes against humanity.
- President's Council on Bioethics

Reference:

Center for Disease Control & Prevention

<http://www.cdc.gov/od/science/regs/hrpp/regAndGuidance.htm>

Discovery, Research and Development of Medication

- “Drugs begin as a single idea in the mind of a gifted scientist”. (Cuozzo, page 34)
- Animal pharmacology and toxicity testing (pre-clinical testing)
- Approximately half of all compounds tested in preclinical trials are eliminated due to safety or metabolism issues.

- Testing for safety, toxicity, and pharmacokinetics is performed
- Drug formulation feasibility
- Drug development may take up to 4 years before it is tested in a clinical trial
- Clinical trials will prove or disprove a drug's efficacy and safety
- Safety must outweigh risk
- Statisticians are needed to determine the sample size
- Blinded or unblinded studies
- Study compounds must be stable, pure, and contain the correct amount of active ingredient
- Safety of study volunteers is always paramount
- Clinical trials will follow FDA regulations
- The study protocol and Informed Consent documents must be approved by an independent institutional review board (IRB) prior to the start of a comprehensive volunteer screening process
- There are multiple study phases (Phase I, II, III, IV)
- Sponsoring companies always analyze the collected data of pilot & phase I studies before moving forward in drug development
- New Drug Application (NDA) and Approval is submitted to the FDA after all three phases of human clinical trials have successfully established safety and effectiveness of the drug
- It takes about 12 years for a drug to get from the "lab to pharmacy" and at a cost of more than \$800 million dollars

Reference:

Cuozzo, CA. How Medications are Born. *Advance for Nurses, New England*. 33-34, December 3, 2007.

Role of Ophthalmic Research Coordinator in conjunction with ASC Staff

- Should clinical research become part of the ASC staff's responsibilities?
- Standard Operating Procedures (SOPs)
 - Human Research Protection Plan
 - Study Management
 - Adverse Experiences
 - Audits/ Inspections
 - Institutional Review Boards
 - Additional Procedures: laboratory & biosafety procedures

Obtaining & Documenting Informed Consent

- Required elements within a consent form
- Additional elements
- Tracking worksheet

Protocol Evaluation

- Confidentiality agreements
- Sponsor Protocol Development Process
- Study Design/ Amendments
- Institutional Review Board (IRB)
- Subject Recruitment

Institutional Review Board (IRB)

- Role of IRB
- IRB membership
- All U.S. clinical trials must be approved by an IRB
- Initial & Continuing approvals

Reference:

<http://clinicaltrials.gov/ct2/info/glossary>

Additional Resources:

Department of Health & Human Services (DHHS) www.dhhs.gov

Food & Drug Administration (FDA) www.fda.gov

National Institutes of Health (NIH) www.nih.gov

Association of Clinical Research Professionals (ACRP) www.acrpnnet.org

Society of Clinical Research Associates (SOCRA) www.socra.org