Scientific Study Blueprint for Licensed Hair Practitioners – Part 1

Use Your Status and Expertise to Advance Science

Week 4

Study Documents – Review

1. Instructions (for the Professional, Study Subject, and/or Institutional Review Board)
2. Consent Form
3. Screener
4. Questionnaire
5. Study Overview for Solicitation/Flyer

CITI Module 1

History and Ethics of Human Subjects Research

Early Problems and the Nuremberg Codes:

There is a history of unethical behavior

Nuremberg War Crimes
Codes

- A requirement for voluntary consent
- Research must have scientific merit
- The benefit of research must outweigh the risks
- Subject have the ability to terminate participation in the research at any time

Henry Beecher Article and PHS Syphilis Study

In 1966 Henry Beecher wrote an article, "Ethics and Clinical Research", which highlighted 22 medical studies published in some of the most prestigious journals. They were shown to present risk to subjects participating in human research that were without the subjects' knowledge or approval.

Better known as the *Tuskegee Exper*iment or *Syphilis Study*, The "Tuskegee Study of Untreated Syphilis in the Negro Male" was conducted by the US Public Health Service (PHS) from 1932 until 1972.

National Research Act

Due to past unethical research, hearings on the "Quality of Heath Care – Human Experimentation" were held before a US senate committee in 1973. Congress passed the 1974 National Research Act.

- Established the "National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research" to identify basic principles and develop guidelines
- Required the establishment of Institutional Review Boards (IRBs) at organizations receiving PHS support

Belmont Report

From the National Commission, the Belmont Report was developed. It identified three basic principles for ethical conduct involving human subjects:

- Respect for Persons
- Beneficence
- Justice

Respect for Persons

"Based on the ethical concept that individuals should be treated as autonomous agents."

Informed Consent
- Information
- Comprehension
- Voluntariness
- Privacy

Beneficence

"The principle of beneficence includes the obligation of researchers to strive to do no harm and to maximize benefits and minimize harms. 'Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.'"

Application of Beneficence
- Systematic assessment of risks and benefits
- Minimization of risk

Justice

"The principle of justice requires that the selection of subjects is equitable. 'Who ought to receive the benefits of research and bear its burdens? …An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly'" (The National Commission 1979)

Application of justice applies to the selection of subjects.

Development of US Regulations

Federal regulations are designed to enforce principles of the Belmont Report and restore public trust in research.

Kefauver-Harris Drug Amendments to the FDA in 1962

- Before then, there was limited power in controlling the marketing of drugs.
- Thalidomide
- In 1966, research abuses led the PHS to issue the policy "Clinical Research and Investigation Involving Human Beings".

Development of US Regulations cont.

The PHS policy was upgraded in 1974 to have regulatory status in 45 CFR 46, the "Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research. (CFR = Code of Federal Regulation)

Additional protections were added in subsequent years:

- Subpart B – Pregnant women, human fetuses and neonates
- Subpart C – Biomedical and behavioral research with prisoners
- Subpart D – Children

International Regulations

In 2001, the World Health Organization (WHO) adopted "Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants." These documents are designed to serve as international guidelines for the review and conduct of research involving human subjects.

In 1996, the International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), an organization that brings together the drug regulatory authorities and the pharmaceutical industry of Europe, Japan, and the United States, adopted standards on Good Clinical Practice (ICH E6). ICH E6 details the responsibilities and expectations of all subjects in the conduct of clinical trials, including researchers, monitors, sponsors, and IRBs. ICH E6 standards, while not part of any country's regulations, provide international standards for transnational pharmaceutical research.

Recent History

From 1974 to the mid '90s, it seemed that everything was going well but…

- There were growing concerns
- Launch of investigations in 1996 by the US General Accounting Office (GAO)
- Death of Jesse Gelsinger

Recent History cont.

The concept of a human research protections program (HRPP) resulted from the findings that concluded that IRBs are not enough to protect human subjects in research.

An HRPP is a comprehensive and organized system of shared responsibility at an organization to ensure the protection of human subjects participating in research. It results in:

- Higher standards for IRB review
- Increased responsibility for researchers
- Increased requirements regarding conflict of interest
- The accreditation of HRPPs