SUN LIFE FAMILY HEALTH CENTER

501-Physicians(s) and Clinical Research in Private Practice... Should I Care?

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Learning Objectives

- Learn definition of research and applicable laws (added)
- Learn basic compliance risks associated with clinical research in practice and how to minimize such risk.
- What you need to know about research and your medical malpractice policy
- Educating your providers down gently.

DISCLAIMER: this presentation does not constitute legal advice, but information & education only

Let's begin...

Research: Taber's Definition

Scientific and diligent study, investigation or experimentation in order to establish facts and analyze their significance.

- **Clinical research** based mainly on bedside observation
- **Laboratory research** done principally in the laboratory
- **Medical research** concerned with any phase of medical science

Which research area has the most compliance or risk issues?

Research: Protections

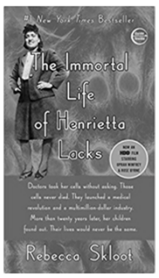
Research protections and required compliance programs:

- Human Research Protections,
- Animal Care and Use, and
- Human Stem Cell Research.

Focus on human research – what needs to be protected?

Reference: University of California, Irvine Office of Research

Research Protections: A Case Study



A few applicable laws

Federal Law - Protection of Human Research Subjects

45 CFR Part 46

Subpart A. *Basic HHS policy* for protection of human subjects

Subpart B. Additional protections for *pregnant women, human fetuses and neonates* involved in research

Subpart C. Additional protections pertaining to *biomedical and behavioral research* involving prisoners

Subpart D. Additional protections for *children* involved as subjects in research

Federal Law - Definitions

45 CFR Part 461.02

(f) *Human subject* - living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

(g) *IRB* - institutional review board established (per the law)

Does anyone know the general function of an IRB?

State Law - Arizona

A.R.S. 36-509. Confidential records; immunity; definition

A. A health care entity must keep records and information contained in records confidential and not as public records... Records and information contained in records may only be disclosed to:

4. Persons doing research only if the activity is conducted pursuant to applicable federal or state laws and regulations governing research.

F. …"information" means records and the information contained in records.

Medical Board

A.R.S. 32-1401. Definitions

27. "Unprofessional conduct" includes the following, whether occurring in this state or elsewhere:

(y) The use of experimental forms of diagnosis and treatment without adequate informed patient consent, and without conforming to generally accepted experimental criteria, including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee as approved by the United States food and drug administration or its successor agency.

Osteopathic Examiners

A.R.S. 32-1854. Definition of unprofessional conduct

"Unprofessional conduct" includes the following acts:

27. Using experimental forms of therapy without adequate informed patient consent or without conforming to generally accepted criteria and complying with federal and state statutes and regulations governing experimental therapies.

Health Professionals

A.R.S. 32-3204. Experimental diagnosis, therapy or treatment; implied consent; definition

A. ….a health professional, within the scope of that person's profession, may use an experimental diagnosis, therapy or treatment on a patient who is unable to make or communicate health care decisions and who has an emergent life threatening condition if the requirements of 21 CFR parts 50, 56, 312, 314, 601, 812 and 814...

B. A health professional who performs an experimental diagnosis, therapy or treatment…is deemed to have obtained the patient's implied consent ...

C. ..."experimental diagnosis" means the pharmaceuticals, devices and technology used to diagnose patients.

AMA and Clinical Research

AMA Journal of Ethics®
Illuminating the art of medicine

Home Current Issue Past Issues Ethics Cases Podcasts

AMA Journal of Ethics. December 2015, Volume 17, Number 12: 1136-1141.
THE CODE SAYS

The AMA *Code of Medical Ethics'* Opinions on Clinical Research

Research Risks

- ❑ Complexity of the regulations and guidelines.
- ❑ Challenge to understand, maneuver and comply with different regulatory bodies requirements.
- ❑ Acting contrary to the laws, regulations or guidelines can cause provider or health professional legal and/or licensing issues.

Minimize Research Risks

Minimize Research Risks

- ❑ Do your due diligence to understand the laws, regulations and guidelines.
- ❑ Use resources such as professional boards and organizations or universities to answer research questions.
- ❑ Do not participate in any research unless you are sure you understand the regulations and guidelines.

Research and Medical Malpractice

State Law - Arizona

A.R.S. 20-1742. Insurers to report malpractice claims and actions

A. Each health care insurer providing professional liability insurance to a health professional (defined in ARS 32-3201) shall report to the appropriate health profession regulatory board…any written or oral claim or action for damages for personal injury claimed to have been caused by:

1. An error, omission or negligence in the performance of an insured's professional services.
2. The performance of professional services without adequate informed consent.

Medical Malpractice Policy

However, provider or health professional may need:

- Clinical Research Liability Insurance (CRLI) or
- Clinical Trial Liability Insurance (CTLI)

In addition to Medical Professional Liability (MPL) insurance

HRSA – Federal Torts Claims Act (FTCA)

Any participants from a HRSA qualifying Community Health Center (CHC)?

Does anyone know what FTCA does?

FTCA and Clinical Research

FTCA Health Center Policy Manual, page 11 states:

C.5.5. Clinical research –

Patient care, conducted by covered individuals with covered entity patients, qualifies for FTCA coverage if it is within the approved scope of project of the covered entity and scope of employment of the covered individual with the covered entity.

Research of non-health center patients is not covered by the FTCA.

FTCA and Clinical Research Example

FTCA Health Center Policy Manual, page 11 states:

C.5.5. Clinical research –

The individual and the entity would be covered if participation in the study is incident to the medical treatment of the covered entity patient. A covered entity provider joins an international clinical research trial comparing 2 pharmacotherapy strategies to control hypertension using covered entity patients with the approval of the covered entity and patients involved.

The individual would not be covered for treatment of non-health center patients as part of the protocol.

Minimize Insurance Risks

Mitigate Liability Risk

Follow best practices –

- ❑ Read the research sponsors contract to determine indemnity / limitations on indemnity (areas, if sued, will be covered or not covered by the sponsor's liability policy)
- ❑ Call your malpractice insurance carrier to confirm your coverage.
- ❑ Add additional coverage as needed.

Provider Education

Practice Considerations – Informed Consent

Taber's Cyclopedic Medical Dictionary

Competent and voluntary permission for a medical procedure, test or medication. The consent is given based on understanding the nature, risks and alternatives of the procedure or test.

Black's Law Dictionary

A patient's knowing choice about a medical treatment or procedure, made after a physician or other healthcare provider discloses whatever information a reasonably prudent provider in the medical community would give to a patient regarding the risks involved in the proposed treatment or procedure.

Practice Considerations – Privacy & Confidentiality

Human Subjects Research

HHS - 45 CFR 46.111(a)(7)

FDA - 21 CFR 56.111(a)(7)

Privacy – control over sharing of oneself (physically, behaviorally or intellectually) with others

- Autonomy of participant
- Beneficence of participant

Reference: University of California, Irvine Office of Research

Practice Considerations – Privacy & Confidentiality

Human Subjects Research

HHS - 45 CFR 46.111(a)(7)

FDA - 21 CFR 56.111(a)(7)

Confidentiality – treatment of participant's information

- In addition to privacy
- Identifiable participant data
- Access to the identifiable data

Reference: University of California, Irvine Office of Research

Practice Considerations – Confidentiality & HIPAA

Health Insurance Portability and Accountability Act of 1996

- Governs Protected Health Information (PHI)
- Disclosure of PHI requires participant authorization (NARROW except treatment, payment or operations, public health, etc.)
- PHI information can be linked to a participant (VERY BROAD)

How many PHI identifiers are there?**

Reference: University of California, Irvine Office of Research

Practice Considerations – Confidentiality & HIPAA Waiver

Preferred: Obtain permission/authorization to use PHI

Secondary: HIPAA allows use PHI for research without obtaining permission/authorization

However: Must be determined by IRB that the 9 WAIVER criteria are met (e.g. minimal risk, not affect privacy rights, not be conducted without use of PHI or waiver)

Reference: University of California, Irvine Office of Research

Practice Considerations – Research Integrity

Principal Investigator (PI)

Responsible for the conduct of research or other activity, described in a proposal for award (i.e. funding). PI is responsible for all programmatic and administrative aspects of the project.

Lead Researcher (LR)

Responsible for meeting all ethical, scientific, and regulatory requirements for conduct of a study protocol (may or may not be the PI)

Reference: University of California, Irvine Office of Research

Practice Considerations – Education & Training

Responsible Conduct of Research (RCR) – Federal training requirements to study personnel as a condition of certain awards (funds)

Be aware some research studies may require additional training

If conducting research in private practice (or a community health center) what other education may be applicable?

Reference: University of California, Irvine Office of Research

References / Resources

Arizona Board of Osteopathic Examiners
https://www.azdo.gov/Statutes-Rules/AZRevisedStatutes ForDOs.aspx

Arizona Medical Board https://www.azmd.gov/LawsRules/LawsRules#

AMA Journal of Ethics
http://journalofethics.ama-assn.org/2015/12/coet1-1512.html

References / Resources

University of California, Irvine Office of Research
https://www.research.uci.edu/about/index.html

U.S. Department of Health and Human Services (HHS), Office for Human Research Protections https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Questions?