Regulatory and Staffing 101 for Clinical Research

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2019 AAD Annual Meeting
U061 - Clinical Trials in Dermatology
03/03/2019, 7:00 AM
March 3, 2019
Washington, DC
DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY

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DISCLOSURES

None; Copies of pdf or questions: bhatiaharbor@gmail.com
Learn your definitions before lawyers or the government teach them to you...

- **Clinical Practice:**
  - Doctors/Clinics: “CE--Covered Entities”
  - Charts: “PHI: Protected Health Information”
  - Disclaimers: “NPP- Notice of Privacy Practices”

- **Clinical Research:**
  - IRB, GCP, ICF, EDC, SOP, FDA

- **Others to remember but not always use:**
  - OMG
  - WTF
  - TSA---get me outta here…
Don’t market clinical research unless you know what you’re doing

- Clinical trials are complicated!
  - A good clinical trials unit is separate but in harmony with a clinic
  - Firewall everything off, keeping clinic charts separate and even have separate waiting rooms if possible
  - Recruiting and converting patients back and forth between private insurance and clinical trials can be tricky but also good for practice

- CMA does not stand for CRC and vice versa

- The foundations of research are regulatory, staff, and the lab
Checkmarks for starting a clinical research unit

- **Business Planning:** incorporating; liability insurance; SOPs

- **GCP Responsibilities:** FDA regulations 21 CFR Parts 11, 50, 54, 56; drug/biologic 21 CFR Part 312; other GCPs, state laws and HIPAA;

- **FDA 1572**

- **Content of Clinical Research SOPs:** Components; training and implementation; measuring compliance; meeting minutes

- **Staffing:** Regulatory, data entry, coordinators, recruiters

- **Marketing a Research Site:** How? To whom? Customers? (sponsors, participants and FDA);
  - Internal marketing from clinic?
Clinical Research is a business

- **Contracts & Budget**: Negotiating contract language; budget components; Working with sponsors
- **Project Feasibility**: What it takes to run a successful study; completing a study feasibility; risk factor analysis and management
- **Subject Recruitment**: Identifying accurate potential subject numbers; methods and strategies; formal recruitment plans
- **Quality Systems and Audit Readiness**: FDA inspection program and site deficiencies; quality system components; establishing audit readiness
Open Payments and Sunshine Act

- Sunshine Act requires reporting of >$10
  - Includes lunches in office which most derms do not attend
  - $9.99 per person still buys a decent lunch
  - Investigator Meetings count too
- Plan on every breath you take being reported
- Hide your prescribing numbers
- Reduce or avoid promotional activities that can cause conflicts with the FDA1572 obligations
Identify Identity Theft

- Fastest-growing type of identity fraud, up over 400 percent in 2008.
- Occurs when a person's name and parts of their identity are used to acquire medical goods or services without that person's consent.
- Often the criminal needs treatment or is uninsured.
- Deception often results in erroneous entries being placed in existing medical records and may involve the creation of false medical records in the victim's name.
- With rising numbers of patients losing health insurance, this will continue to become a problem.
- Source documents require all information that is relevant to the patient be available for review by a monitor or during an audit.
  - Screening visits are the branchpoint.
During the Typical Paper Day...

- Are the charts and research source documents in a protected area or loose all over the clinic or in a doctor’s car?
- Is the insurance and patient information attached or separate?
- Auditors and Monitors feast on these arrangements!
And who is watching the computers?

- Does the EMR vendor provide on-site backup tapes or is it all virtual?
- Are the computers that contain important patient data files backed up and adequately protected from, spam, virus and tampering?
- Are the important documents about the practice backed up in 3 places - memory sticks, CD-ROM, Ext. hard drive?
- How many people are in charge of these? At least more than one in case the primary person gets sick, leaves, or dies.
Are Research Subjects Customers or Patients?

- Customers choose to do business with a certain establishment
  - As a result, the establishment’s revenue increases.

- Customer service is a business idea developed to attract and retain profits.

- Physician-Patient relationship is profit driven

- Patients needing health care may positively, neutrally or even negatively affect revenue.
  - Patients may carry good, poor or no insurance.
  - Institutions are legally obligated to care.

- Physicians’ obligations for their patients does not translate to the language of customer service.

- It an be difficult when a research patient needs medical care and you are not allowed to provide it.