Unit IID Quiz

National Institutes of Health, "Clinical Research and the HIPAA Privacy Rule", June 22, 2004, pp. 1-5 [link]

1. The HIPAA Privacy Rule applies to "Covered Entities" (45 CFR §160.103, link) defined as which of the following:
   a. treatment, payment and healthcare operations
   b. health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form
   c. medical researchers, business associates, and health information organizations
   d. none of the above

2. Under the HIPAA Privacy Rule, in order for a covered entity to use or disclose protected health information for research purposes without the authorization of the patient, a waiver must be obtained from which of the following (45 CFR §164.512(i)(1), link):
   a. an Institutional Review Board (IRB)
   b. a Privacy Board
   c. either of the above
   d. none of the above

3. Under the HIPAA Privacy Rule, in order for a covered entity to use or disclose health information for research purposes without the authorization of the patient, and without an IRB/privacy board waiver, the health information must satisfy which of the following (45 CFR §164.514, link):
   a. be de-identified in accordance with the standards of the Privacy Rule
   b. be a limited data set in accordance with the standards of the Privacy Rule, with respect to which the recipient has entered into a data use agreement
   c. either of the above
   d. none of the above

4. The HIPAA Privacy Rule provides that "de-identified information" that meets the standards for "de-identification" in the Privacy Rule is no longer subject to the Rule, unless and until "re-identified", for which of the following reasons (45 CFR §164.502(d)(2), link):
   a. Medical researchers are never "covered entities" subject to HIPAA
   b. Medical research is governed exclusively by the Common Rule
   c. The Privacy Rule applies to protected health information (PHI, 45 CFR §160.103), which is a subset of individually-identifiable health information (IIHI, 45 CFR §160.103); "de-identified information" is considered not to be IIHI
   d. All of the above

5. The HIPAA Privacy Rule applies certain obligations upon "Business Associates" (45 CFR §160.103, link) who provide certain functions or services on behalf of a Covered Entity that require use or disclosure of Protected Health Information (PHI), including which of the following:
   a. data analysis, processing or administration

b. data aggregation
c. data transmission services that requires access on a routine basis to PHI
d. all of the above

6. Under the HIPAA Privacy Rule, to be valid an "Authorization" (45 CFR §164.508(c)(1), link) from an individual permitting a Covered Entity to use or disclose PHI for a research study must satisfy certain core elements, which include which of the following:

a. a description of the PHI to be used or disclosed
b. specific identification of the persons authorized to make the use or disclosure, and of the recipients
c. a description of each purpose of the requested use or disclosure
d. all of the above

McWay, Dana C., Legal and Ethical Aspects of Health Information Management (3d ed., 2010), Chapter 10 "Access to Health Information", pp. 210-215 ("Access by the Researcher")

7. Which of the following practices by medical researchers have been challenged as unethical:

a. failure to disclose material information to test subjects
b. employing coercive or deceptive tactics
c. taking advantage of a vulnerable population
d. all of the above

8. Federal HHS regulations (45 CFR §46.111; link) that govern research involving human subjects require an Institutional Review Board (IRB) to determine satisfaction of which of the following criteria:

a. the risks to human subjects are reasonable in relation to the anticipated benefits
b. informed consent will be sought from each human research subject and documented
c. the selection of human subjects will be equitable and cognizant of the special problems involving vulnerable populations
d. all of the above

9. Additional safeguards in a research study which protect the rights and welfare of certain subjects may be appropriate for which of the following populations as considered vulnerable to coercion or undue influence (45 CFR §46.111; link):

a. children
b. pregnant women
c. economically or educationally disadvantaged persons
d. all of the above

10. Under the HIPAA Privacy Rule a "de-identified" data set (45 CFR §164.514(b), link) is smaller than the "limited data set" (45 CFR §164.514(e)) of the same data in regard to which of the following identifiers:

a. geographic identifiers
b. elements of dates, including birth, death, admission and discharge

c. both of the above
d. none of the above

Institute of Medicine, Beyond the HIPAA Privacy Rule (2009), Summary pp. 1-13 [link]

11. The Institute of Medicine (IOM) in its 2009 report "Beyond the Privacy Rule" concluded that the HIPAA Privacy Rule impedes important health research for which of the following reasons:

a. it conflicts with other federal regulations governing health research
b. it is interpreted differently across institutions
c. it creates barriers to research and leads to biased research samples, which generate invalid conclusions
d. all of the above

12. The IOM (2009) concluded that requiring informed patient consent in information-based research (e.g., using medical records or stored biological samples):

a. would not be needed to protect research participants from physical harm
b. would be prohibitively costly and difficult to obtain for analysis of very large data sets
c. could lead to invalid results because of significant differences between patient participation choices
d. all of the above

Jacques, Lauren, "Clinical Research Considerations in Light of the Final HITECH Rule", Jan. 29, 2013 (© 2013 American Health Lawyers Association)

13. The Privacy Rule provides which of the following two methods for PHI de-identification (45 CFR §164.514(a), link):

a. limited data set and designated record set
b. data mining and digital fracking
c. expert determination and safe harbor
d. none of the above

14. The Privacy Rule provides which of the following qualifications for the utilization of an expert for PHI de-identification (45 CFR §164.514(a), link):

a. the expert determination must have a stated expiration date
b. the expert determination methods and results must be documented
c. the expert determination must establish that the level of identification risk is below a specified numerical level
d. the expert must possess one of the specified professional degrees or certifications

15. In providing guidance in 2012 regarding methods for de-identification of Protected Health Information, HHS noted that under either of the two de-identification methods provided by the Privacy Rule, there remains some risk of identification, although small. Which of the following subsequent

developments might increase the risk of de-identified data being linked back to the identity of the patient to which it corresponds:

a. The implementation in the US of a universal patient ID number system to facilitate the linking of patient records in different data sets
b. Improvements in “big data” mining software and hardware capabilities
c. Increased volume, diversity and availability of collected data sets
d. All of the above

16. A potential benefit of achieving de-identification of PHI in accordance with the standards of the Privacy Rule utilizing the “expert determination” method rather than the “safe harbor”:

a. identifiers that may be desired for the intended research that are completely excluded under the safe harbor approach may be included to some degree under the expert determination
b. the expert may attach an expiration date to his/her determination, limiting its validity
c. the professional qualifications of the expert chosen by the covered entity may be challenged
d. the expert’s documented methods and results of the analysis that justify the determination may be challenged