Davis Wright Tremaine LLP

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1.03: IRBs in the Community Hospital Setting with Particular Attention to HIPAA Compliance, State-Specific Consent Law, the Central IRB Project, Tissue Banking Initiatives, and Other Hot Topics

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HIPAA Compliance

- Potentially overwhelming responsibility. However, as a practical matter, most community hospital IRBs will focus almost entirely on the basic authorization requirements, which can be incorporated in the body of conventional research consent forms.
- Core Elements of Consent/Authorization for Use or Disclosure of Individually Identifiable Health Information.
  - A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;
  - The name or other specific identification of the person(s), or class of persons, authorized to make use of or to disclose the information;

HIPAA Compliance

- Core Elements of Consent/Authorization *(cont'd)*:
  - The name or other specific identification of the person(s), or class of persons, to whom the information may be disclosed;
  - A description of each purpose of the use or disclosure;
  - An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for use or disclosure of Individually Identifiable Health Information for research, including the creation and maintenance of a research database or research repository; and

HIPAA Compliance

- Core Elements of Consent/Authorization *(cont'd)*:
  - The signature of the individual and date (which may appear at the end of the consent form). If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.
- Required Statements Regarding the Use or Disclosure of Individually Identifiable Health Information.
  - The individual's right to revoke the authorization in writing, and either:
    - The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

HIPAA Compliance

- Required Statements *(cont'd)*:
  - To the extent that the information referenced in the above paragraph is included in the Hospital's Notice of Privacy Practices, a reference to that Notice;
  - The consequences of the individual's refusal to sign the authorization with reference to the provision of research-related treatment, payment, enrollment or eligibility for benefits; and
  - The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected by the terms of use and disclosure otherwise described in the authorization.

HIPAA Compliance

- Other topics involving exceptions to authorization requirements:
  - Reviews preparatory to research
  - Research on decedent's information
  - Waiver or alteration of authorization
  - De-identified information
  - Limited data sets

HIPAA Compliance

- Accounting for disclosures without authorization – who will bear the burden?
- The biggest immediate challenge will be to assure that all consent forms for studies open to new enrollment as of April 14, 2003, contain HIPAA compliant language for anyone who signs after that date. Issues:
  - Who is responsible for preparing that language?
  - Can consent form modifications to comply with HIPAA be approved by expedited review?

Specimen Banking

- Study sponsors, most notably cooperative oncology groups, are increasingly interested in collecting biological specimens for use in unspecified research.
- Typically tied to specified clinical studies, to which subjects consent separately.
- The activities have out-paced the establishment of clear policies, resulting in confusing, inconsistent, and probably inaccurate information being given to patients to solicit consent.
- Challenges to the IRB:
  - Identify this as a separate activity, where it exists as such.
  - Determine the policies of the entity administering the program.
  - Assure that consent forms clearly and accurately present material information.

Specimen Banking

- Consent Issues:
  - Is clinical study participation contingent on consent to related or unrelated specimen banking?
  - What will be taken – tissue? blood? sputum?
  - What are the physical risks, if any?
  - What are the clinical risks, if any? For example, will a specimen be exhausted, leaving no remaining sample for treatment use if necessary or potentially beneficial?
  - Will data be reported back or available to the patient or treating physician?
  - Will the patient otherwise benefit personally?

Specimen Banking

- Consent Issues *(cont'd)*:
  - Will patient have a proprietary interest in the specimen if it is sold or used to develop products for a profit?
  - What are the privacy risks? Will the specimen bear identifiers? Can it be traced back to the patient through a code? What are the HIPAA implications?
  - Is consent revocable? What are the practical limits?
  - Should the nature of the research (for example, cancer or Alzheimer's) be described as a consent factor?
  - Should the patient be asked about willingness to be contacted about other research opportunities in the future?

Central Institutional Review Board Initiative

- Special project administered by NCI to streamline local review and approval process for Phase 3 NCI-sponsored studies.
- Described at www.ncicirb.org.
- Local investigator who wishes to enroll subjects in a CIRB-approved study downloads protocol, informed consent documents, and CIRB application from website and submits to local IRB.
- Designated local IRB member reviews in accordance with locally-specified authority. For example:
  - Identifies local issues.
  - Determines appropriateness for local facility, including qualifications of investigator.
  - Determines whether full IRB review is warranted.

Central Institutional Review Board Initiative

- Local IRB options, subject to cooperative group approval:
  - Add stipulations or local requirements to increase patient safety or clarify procedures, short of deleting or contradicting protocol requirements.
  - Conform consent form to local boilerplate.
  - Conform to local law, institutional or IRB policies.
  - Approve or reject.

Central Institutional Review Board Initiative

- IRB will need to establish special policies and procedures, specifying, for example:
  - The scope of the initial reviewer's responsibilities
  - The role of the IRB in giving final approval and establishing contingencies, if any
  - The mechanism for monitoring and periodic review
- Advantages:
  - Efficiency and reduction of work-load
  - Review and approval of covered studies at any time, without regard to IRB's meeting schedule
- Disadvantages:
  - Unknown

Research Related Problems – Suspension or Termination

- The IRB is primarily responsible for establishing and enforcing standards of propriety in the research that comes under its jurisdiction. From time to time, it will be confronted with issues of law, compliance, or ethics, with or without related harm to patients.
- Fundamental principle: The IRB has jurisdiction over the approval and regulation of research. It is not authorized to regulate, and should take care to avoid the appearance of regulating, clinical privileges or hospital employment. Consider:
  - Medical Staff Bylaws.
  - State and Federal Laws, including Health Care Quality Improvement Act, with formal hearing and reporting implications.
  - 42 CFR Part 50 – Responsibilities of PHS Awardees and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science.

Research Related Problems – Suspension or Termination

- IRB Policies and Procedures
  - Research approved by the IRB may be subject to further review and approval by other institutional officials, but federally-regulated research NOT approved by the IRB may NOT be approved by other institutional officials (21 CFR 56.112; 45 CFR 46.112)
  - Action by Chair
    - Preliminary inquiry
    - Immediate remedial measures

Research Related Problems – Suspension or Termination

- IRB Policies and Procedures *(cont'd)*:
  - Action by IRB
    - Broad options, including immediate action based on available data or further investigation.
  - Formal investigation
  - Notice and opportunity to be heard
  - Reporting
  - Records