Davis Wright Tremaine LLP

Advanced Medical Research Disclosure and Consent Issues

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The Issues

① Use and Disclosure of Private Health Information for Research Recruiting Purposes

② Special Issues Regarding Humanitarian Use Devices

③ Managing Conflicts of Interest within the IRB

Use and Disclosure of Private Health Information for Research Recruiting Purposes

- The HIPAA Privacy Regulations establish several grounds for an IRB to approve a waiver of the authorization requirements. For example, a waiver may be approved to allow for the use or disclosure of Protected Health Information (PHI) "as necessary to prepare a research protocol or for similar purposes preparatory to research." (45 CFR 164.512(i).)
- However, there is no regulatory basis for allowing PHI to be used or disclosed solely for purposes of ascertaining whether an individual is eligible to participate, or willing to consider participating, in a research protocol.

Use and Disclosure of Private Health Information for Research Recruiting Purposes (cont'd)

- As a matter of institutional policy, it is not a good idea to allow patients to be approached by someone who is not directly involved in their care for purposes of exploring their willingness to consider participating in a research protocol.
  - It can conflict with the wishes of the treating physician, based on considerations relating to the patient's mental or physical condition.
  - It can be viewed by the patient as an intrusion.

Use and Disclosure of Private Health Information for Research Recruiting Purposes (cont'd)

- Judging from recent exchanges on the IRB listserve (www.irbforum.org/discussion), is it commonplace for institutions to maintain a policy that potential participants in research protocols be approached initially only by someone with an established treatment relationship, who is already privy to the PHI.
- Ideally, the initial contact will be made by the treating physician, or by a member of his or her staff with the physician's express permission.

Use and Disclosure of Private Health Information for Research Recruiting Purposes (cont'd)

- A special Authorization form should be used, clearly explaining:
  - That permission is being sought to disclose information only for purposes of:
    - Allowing others, as specified, to determine whether the patient is eligible to participate in a research protocol; and if so,
    - Allowing others, as specified, to approach the patient, provide more information (including a research consent form), and give the patient an opportunity to consent to participate.
  - The nature of the information to be disclosed.
  - How the information will be maintained.
  - What will happen to the information once its purposes have been served.
  - The patient's right to revoke the authorization.
  - That the patient is free to decline to give the authorization, and that it will not affect the patient's care.

Use and Disclosure of Private Health Information for Research Recruiting Purposes (cont'd)

Model Elements

- Purpose of this Form
  - Researchers who are affiliated with [*insert name of hospital or other entity*] are conducting a study in which you are, or may be, eligible to participate. Before the researchers can fully explore your eligibility or invite you to participate in the study, they and/or their staff will need to be told or given access to certain personal health information about you, as described below. This form authorizes your physician or other care-givers to disclose your personal health information for these purposes. Please note that signing this form does NOT mean that you are consenting to participate in any research. It only means that your personal health information may be used for the limited purposes described. If you are eligible to participate in the research, you will be offered an opportunity to sign a separate consent form expressly for that purpose.

Use and Disclosure of Private Health Information for Research Recruiting Purposes (cont'd)

- **Personal Health Information Being Disclosed**
  - In order to determine your eligibility and/or willingness to participate in the research study identified below, it is necessary for the researchers and/or their staff to receive individually identifiable personal health information, which is known to your physician and care-givers and/or is in your medical record. Such information may include the following:
    - The history and status of your disease or condition;
    - Specific information about treatments you have received, including previous treatment(s) you may have had;
    - Information about other medical conditions;

Use and Disclosure of Private Health Information for Research Recruiting Purposes (cont'd)

- **Personal Health Information Being Disclosed** (cont'd)
  - Medical data, including, laboratory test results, CT scans, MRIs, x-rays, and pathology results;
  - Information about side effects, complications or other problems that you may have experienced, and how these were treated;
  - Information about your general health status and history;
  - Information related to tissue and/or blood samples that may have been (or may be) collected from you; and
  - Numbers, codes or other information that will identify you, such as your name, address, age, weight, gender, ethnic origin, social security number and medical record number.

Use and Disclosure of Private Health Information for Research Recruiting Purposes (cont'd)

- **Use of Personal Health Information**
  - The researchers and their staff will use your information in connection with their study entitled: [*insert title of study*].
- The purpose of this study is: [*insert summary of study*]
- The researchers and their staff, in the course of their activities, will not remove any individually identifiable personal health information from this facility, nor will your personal health information be further disclosed in a way that would identify you.

Use and Disclosure of Private Health Information for Research Recruiting Purposes (cont'd)

- **Voluntary Permission**
  - You have the right to refuse to sign this authorization form. Refusal to sign this authorization form will not in any way affect your medical care. If you do sign this form, your authorization will remain in effect until its purposes have been served as described above, regarding the specific study identified in this form. You may withdraw your authorization by notifying your physician or the care-giver to whom you gave the authorization, and your personal health information will not be disclosed after that point. It may or may not be possible to prevent any further use of information that has already been disclosed or used as initially authorized by you.

Special Issues Regarding Humanitarian Use Devices

- A Humanitarian Use Device ("HUD") is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. The FDA's regulations, 21 CFR 814.124 Subpart H, provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations, by exempting them from certain requirements that apply to other devices.

Special Issues Regarding Humanitarian Use Devices

- A Humanitarian Device Exemption ("HDE") application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. However, the application must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.
- The applicant must also demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.

Special Issues Regarding Humanitarian Use Devices (cont'd)

- An approved HDE authorizes marketing of the HUD. However, a HUD may only be used in facilities that have established a local IRB to supervise clinical testing of devices and after an IRB has approved the use of the device to treat or diagnose the specific disease.
- The labeling for a HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.
- The following questions and answers appear on the FDA's Website, as "Final Guidance for Industry":

Special Issues Regarding Humanitarian Use Devices (cont'd)

- What types of reviews are IRBs responsible for with respect to HUDs?
  - IRBs are responsible for initial as well as continuing review of the HUD. For initial review of a HUD, IRBs are required to perform a full board review. For continuing review, however, IRBs may use the expedited review procedures (section 56.110) unless the IRB determines that full board review should be performed. The agency believes that the expedited review procedures are appropriate for continuing review since the initial review would have been performed by the full board and use of a HUD within its approved labeling does not constitute research.

Special Issues Regarding Humanitarian Use Devices (cont'd)

- Does an IRB have to review and approve each individual use of the humanitarian use device (HUD)?
  - No. The IRB does not need to review and approve individual uses of a HUD. As long as the use of the HUD is within the FDA-approved indication, the IRB may approve use of the device however it sees fit. That is, the IRB may approve use of the HUD without any further restrictions, use of the device under a protocol, or use of the device on a case-by-case basis. In reviewing use of the HUD, IRBs should be cognizant that the use of the device should not exceed the scope of the FDA-approved indication.

Special Issues Regarding Humanitarian Use Devices (cont'd)

- Is informed consent required when treating/diagnosing a patient with a HUD?
  - The Federal Food, Drug, and Cosmetic Act (the act) and the HDE regulation do not require informed consent because a HDE provides for marketing approval, and so use of the HUD does not constitute research or an investigation which would normally require informed consent. Although neither the act nor the regulation requires informed consent, there is nothing in the law or regulation that preempts a state or institution from requiring prospective informed consent. Most HDE holders, however, have developed patient labeling that incorporates information to assist a patient in making an informed decision about the use of the device. That is, the patient labeling contains a discussion of the potential risks and benefits of the device as well as any procedures associated with the use of the HUD. It also states that the device is a humanitarian use device for which effectiveness for the labeled indication has not been demonstrated.

Special Issues Regarding Humanitarian Use Devices (cont'd)

- A physician has a legal and ethical duty to obtain the patient's informed consent to medical treatment. It arises from the fiduciary quality of the physician-patient relationship, which is based on the patient's dependence on the physician's specialized knowledge. (*Cobbs v. Grant*, 8 Cal.3d 229 (1972).) Failure to obtain the patient's informed consent for a procedure that is not simple and common, or does not involve commonly understood risks and benefits, may result in a charge of battery and/or medical malpractice.

Special Issues Regarding Humanitarian Use Devices (cont'd)

- IRBs should require a written consent form, explaining:
  - The nature and purpose of the device.
  - That the device has been approved by the FDA as a Humanitarian Use Device, which is intended to benefit patients having a condition that affects relatively small numbers of people.
  - That, to assure the availability of such devices, the FDA does not require them to meet the same testing requirements for effectiveness that apply to other commercially available devices.
  - That, to qualify for approval, the device manufacturer was required to demonstrate that there are no comparable devices available to treat patients for the same condition, and that the manufacturer could not otherwise bring the device to market.
  - The available alternatives, if any, and the anticipated consequences of not using the device.

Managing Conflicts of Interest within the IRB

- A member of the IRB may not participate in the initial or continuing review of a study in which he or she has a conflict of interest, except to provide information requested by the IRB.
- Problem: How is this issue to be managed, as a practical matter?
  - Routine annual or other periodic disclosures would not suffice, because one cannot foresee all of the studies that will be presented for approval in between.
  - Routine solicitation of disclosures at meetings would not suffice, because:
    - Members may be wary of openly discussing personal information or raising issues about which they are uncertain
    - There would be a potential for awkward deliberations with inappropriate results
    - There would be a potential for time-consuming diversions from the IRB's scheduled business.
- Suggested solution: A cover sheet for IRB meeting materials, reminding IRB members of their obligations and providing a mechanism to address any issues in an orderly and appropriate manner. Model:

Managing Conflicts of Interest within the IRB (cont'd)

- **Note Regarding Conflicts of Interest**
  - Please be reminded that a member of the IRC may not participate in the initial or continuing review of a study in which the member has a conflict of interest, except to provide information requested by the IRB.
  - A conflict of interest exists whenever a person's judgment might be influenced by factors other than the criteria described in the IRB's written procedures for considering study proposals or other matters. Such circumstances include, but are not limited to, those in which:
    - A person is an investigator in or sponsor of a study;
    - A person has a financial stake in the entity sponsoring the study; or
    - A person otherwise stands to benefit financially or otherwise from the enrollment of patients in the study or from the results of the study.

Managing Conflicts of Interest within the IRB (cont'd)

- **Note Regarding Conflicts of Interest** (cont'd)
  - If you have a conflict of interest in any matter referenced in the enclosed materials, please disclose this to the IRB Chair in advance of any discussion of that matter by the IRB, and refrain from participating in any aspect of the IRB's activities regarding that matter.
  - On your own initiative, or at the discretion of the Chair, you may be excused from the IRB meeting when that matter is discussed. Your disclosure and non-participation will be duly noted in the IRB's records.
  - If you believe that you might have a conflict of interest but are uncertain, please consult with the IRB Chair as soon as possible, so that the issue can be addressed and resolved efficiently and appropriately.