iConsent

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In medicine, a "consent form" is the legal instrument through which we must give our patients sufficient information (positive, such as benefits, and negative, such as risks and complications) regarding any treatment or procedure they will receive. The idea behind it is that an informed patient can accept or more importantly decline a treatment (for personal and/or religious reasons) even if the physician disagrees with this decision. The key word here is "physician." A consent form, under most circumstances, must be administered only by a full-fledged physician, never a medical student, nurse, or technologist. The attending physician can (and does in many academic centers) delegate obtaining consent to a resident or fellow (who already is an MD). In the United States, minors cannot give consent and their parents or legal guardians must give it.* Patients in extreme emergency situations and those with limited cognition are exceptions; and when no family member or legal guardian is available, 1 or more physicians may sign the patient's consent form. As we get older and move into specialized care institutions far away from our families, the caregiver may consent to emergency treatments. The Caregiver Consent Form must be prepared in advance; a lawyer is not needed in the decision making process. For parentless children, a similar form can be used. Consent forms from parents, grandparents, and others are available in most large institutions.

The most common consent form used is, however, the generic one. Regardless of their specifics, all consent forms must meet certain minimum legal standards. Any impairment of reasoning faculties and/or judgment (including previous sedation) makes it impossible (and illegal) to administer the consent form, regardless of its type. Waivers of consent may also be obtained and are not uncommonly used by large institutions such as the Army when a treatment involves minimal risk, benefits the patient, advances medicine, and is carried out under laws established by the US Food and Drug Administration.[1] The need for consent is so ever-present that there are commercial companies that specialize in designing and administering these forms.

Access to the Internet and medical knowledge has considerably changed many aspects of consent. Until a few decades ago, medical treatment was administered following the concept that "doctors know better." This idea originated in Greece and follows the precepts of the Hippocratic Oath.[2] Many of us become irritated when patients try to steer their treatments (coil embolization versus clipping of intracranial aneurysms is a typical example) on the basis of information found on the Internet because we have been brought up to believe in the Hippocratic Oath (ie, we know better). This concept did not really change until the 18th century, when doctors began to believe that sharing as much information as possible with patients was beneficial, but in the end, physicians always made the most important and final decisions. The idea the "doctor knows better" has been called "benevolent deception," and it has been fought against since the mid-1800s. In the United States, the most important aspect of consent is "what is being said" rather than "who is saying it" and "where it is being said" (this may not be the case in other cultures and countries).

As we now know it, the consent form is a recent invention and stems from the consequences of various unethical (to say the least) situations during and around World War II. After the war trials against illegal human experiments by Nazi physicians, the Council for War Crimes published the "Nuremberg Code."[3] This set of rules defines legitimate medical research and is accepted by the Declaration of Helsinki and the US Department of Health and Human Services and is incorporated into the law in many states and countries. One of the most important aspects of the "Nuremberg Code" is informed consent without coercion. Violations of the Code continued after the War even in the United States. Perhaps the best known is the "Tuskegee Syphilis Experiment."[4] This experiment (if one can call it that) extended for 40 years (up to 1972) and was "administered" by the US Public Health Service in Tuskegee, Alabama. In it, the natural progression of syphilis was assessed while infected patients thought they were getting the appropriate medical treatment. Six hundred poor African American agricultural workers were recruited, and 400 who had syphilis went untreated (they were given free burial insurance by the government). Remember that 15 years after the beginning of the "experiment," there was irrefutable scientific evidence that penicillin (widely available by then) was the standard treatment for syphilis. Although this is not the only occasion of human rights violations, it is certainly the most infamous one, and in 1978, it led to the "Belmont Report," which sets the guidelines for the protection of subjects in clinical and research trials in health care.[5] The report led to the creation of the Office for Human Research Protections and Institutional Review Boards (IRBs) in medical schools, academic centers, and hospitals.

IRBs are decentralized committees that review and monitor biomedical research in humans. IRBs themselves are overseen by the Office for Human Research Protections. Before becoming an IRB member at any institution, any conflict of interest (such as working for the industry as a consultant) must be disclosed. IRBs must comprise at least 5 experienced individuals (both male and female), have representatives of different professions (scientists versus nonscientists), and include community members.[6] All research projects and, in many institutions, all publications must be granted permission by an IRB. These IRBs approve research projects only when bona fide consent will be obtained from all participants. When the project is closed, most IRBs require notification and summary of the results.

Most of us who have been (or are) involved in research know how difficult and lengthy the process of IRB approval is. Many blame the relative decline of US research on this while other coun-

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tries with less complex approval processes are making headway in research. To ease the process, many IRBs offer exemptions. In medicine, the most common exemption is for research that involves the analysis of already-existing data as long as the identities of the subjects are protected. For this, some IRBs have special shorter forms while others demand that their long forms be completed. For most exemptions, consent from individual subjects is not required. The problem with IRBs is that data obtained from patients are so closely guarded that access is not available to other researchers who would benefit from them. Just try getting your own data after participating in a research project that has been completed. Even worse, try getting your own medical record released. The owner of the medical record is not the patient but the health service provider who created it, and similarly, the owner of data collected during research is the institution or company funding the project and not the subjects.

Research data are kept in "information silos" understandably guarded from prying eyes but also fragmented. Similar to grain silos that house one type of product, data collected are mined only for proving or disproving a specific hypothesis, and all other information contained in the silo is not used. In this era of fast computing, data transfer, and crowdsourcing and sharing, this process may not be the best way to advance science. "Open source" medicine and research are coming our way, and we need to adapt more than our consent forms to take advantage of them. Apple (Cupertino, California) and Google (Mountain View, California) already keep track of an enormous amount of personal data; Microsoft (Bothell, Washington) keeps track of all data transmitted by using their products such as Outlook for e-mail and calendars. Very soon, science will not survive without data-sharing, integration, and networking. It could be that the consent form that was created to protect us is now, in its current form, detrimental to science.

John Wilbanks has created the WeConsent.us Web site and data base (http://weconsent.us/).[7] Mr Wilbanks said, "All too many observations lie isolated and forgotten on personal hard drives and CDs, trapped by technical, legal and cultural barriers." A critical and innovative aspect of this idea is the use of a special consent form that states that if kept anonymously, your (and my) medical data (particularly health and genomics) can be used by third parties as long as our identity remains protected. This consent is called a "Portable Legal Consent" because you carry it with you, and you attach it (thus its portability) to any data you want to donate. Think about it as having a consent form in your iPhone (Apple) and electronically transmitting it when you need. Personally, I would not mind sharing my medical data if my identity is protected, but I cannot do this because I do not own it! Mr Wilbanks stated that we need to move from information silos to "information commons."

Vanderbilt University (in collaboration with Northwestern University) has started a DNA biorepository and combining it with electronic medical records, an information commons expected to shed light on diabetes, Alzheimer disease, and heart disease is being built.[8] When asked, nearly 95% of patients state that they would be willing to share their medical data.[9] Applications for the iPhone (ie, MyMedical) that allow you to keep your own medical record and share all or parts of it are available. The Eatery application allows you to photograph what you eat and share it (anonymously) with other users to try to improve your eating habits. The goal of the WeConsent.us Web site is to get 100,000 individuals in its first year (and 1 million in 5 years) to donate their medical data, which will then be available for analysis by mathematicians and other scientists.

The future of medical research lies in its power, and its power lies in numbers. However, this power can only be realized if we own our data and we consent to share it. Data accumulated with time do not have to wait to be uploaded and shared but should be dynamically shared in real time. Imagine carrying your own consent form in your mobile device and attaching it to newly available data that you can share when you want to. This consent form could be malleable and would adapt to different needs and situations, taking advantage of the incredible interaction possible on the Web. I think that the time for the iConsent is here.

*In other countries (especially England), the Gillick standard states that a child younger than 16 years of age may, under certain circumstances, be judged mature enough to consent.[10]

REFERENCES

1. McManus J, Mehta SG, McClinton AR, et al. **Informed consent and ethical issues in military medical research.** *Acad Emerg Med* 2005;12:1120–26
2. Informed consent. Wikipedia. http://en.wikipedia.org/wiki/Informed_consent. Accessed October 24, 2012
3. Nuremberg Code. National Institutes of Health. http://history.nih.gov/research/downloads/nuremberg.pdf. Accessed June 20, 2012
4. Tuskegee syphilis experiment. Wikipedia. http://en.wikipedia.org/wiki/Tuskegee_syphilis_experiment. Accessed October 24, 2012
5. Sims JM. **A brief review of the Belmont Report.** *Dimens Crit Care Nurs* 2010;29:173–74
6. Institutional Review Board. Wikipedia. http://en.wikipedia.org/wiki/Institutional_Review_Board. Accessed October 24, 2012
7. John Wilbanks: let's pool our medical data. http://www.ted.com/talks/john_wilbanks_let_s_pool_our_medical_data.html. Accessed October 24, 2012
8. The eMerge Network. http://emerge.mc.vanderbilt.edu. Accessed October 24, 2012
9. Most consumers willing to share personal data. NorthPoint Domain. http://www.northpointdomain.com/default/index.cfm/expertise-and-insight/iq360-insight/industry-spotlight/most-consumers-willing-to-share-personal-data. Accessed October 24, 2012
10. Gillick competence. http://en.wikipedia.org/wiki/Gillick_competence. Accessed October 24, 2012