value received by individual consumers. One could also promote the collective view that the services available to consumers collectively form a "zero-sum" game in which all will get more if the collective waste is minimized. One way or another, waste has to be viewed negatively, rather than as enhanced income.

PATIENT PRIVACY AND CONFIDENTIALITY

Stolen laptops with personal data are frequently in the news. Increasingly, however, the potential content of electronic patient records, digitized information already collected for billing and claims, and specialized databases offer the potential for finding out more about disease processes and care outcomes. At the same time, they offer possibilities for excluding individuals from care or for breaches of the confidentiality that one expects when encountering the health care system. This is an area where tradeoffs will continue to be difficult and frustrating and will continue to be important in policy analysis and decision making.

INFORMED CONSENT

Requirements for informed consent for patients and human subjects in research represent a constraint on provider autonomy. They added to the staff burden, but are a regulatory requirement. **Table 11-1** illustrates part of the federal regulations governing informed consent by research subjects in federally funded research. You might ask yourself this: What values are represented here, and why were they made an added requirement of all research in the first place?

PERSONAL RESPONSIBILITY

A significant portion of the cost of health care can be attributed to patient lifestyle choices, such as smoking, lack of exercise, overeating or poor nutrition, not wearing seat belts and cycling helmets, and overuse of drugs and alcohol. Many policy proposals seek to change the behaviors that put one at risk or to shift those costs to the individuals at risk. Smokers pay higher insurance premiums for long-term care, for example. Analysts suggest that those involved in risky behaviors, such as not wearing motorcycle helmets, post a bond to cover their incremental medical care costs in case of an accident. The discussion of health care insurance is full of references to mora

TABLE 11-1 45 Code of Federal Regulations §46.116: General Requirements for Informed Consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(continues)

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

Other sections allow further exemptions where this procedure might interfere with state and local requirements or with emergency medical treatment.

hazard and the free-rider problem. Most people would agree that individuals should take more responsibility for their behavior rather than have it borne as a collective risk, but there is less agreement on the effort society should expend to make healthy choices more attractive. There is considerable evidence, for example, that the development choices we make—our *built environment*—can encourage or discourage physical activity. A politician asked to support a bill to encourage "walkability" or "multimodal transportation hubs," however, may be inclined to attribute lack of exercise solely to, as one state legislator once put it, "a lack of personal fortitude."