Imagine that you are Dr Stellar Educator and for the last 5 years you have been teaching a course on professionalism to medical students. As part of the course, you have collected data on attitudinal changes of the course participants. The collected data have been impressive, and you would now like to share your data with the academic world by publishing the results in *Family Medicine*. As you prepare the manuscript, a colleague mentions something about needing approval by your local Institutional Review Board (IRB), and you wonder whether this is really necessary. Is educational research subject to the same standards and expectations as is clinical biomedical research? This paper’s purposes are to answer this question and to review the standard requirements for human subjects protection in educational research.

**Historical Background**

Edward Jenner, an English country physician, performed one of the earliest documented research trials involving human subjects. During the course of his work, he recognized that dairymaids infected with cowpox were subsequently immune to smallpox. He then deliberately infected James Phipps, the 8-year-old son of his gardener, with cowpox in 1796 and then later exposed him to smallpox. The boy failed to contract smallpox. After repeating the experiment on other children, including his own 18-month-old son, Jenner concluded that cowpox vaccination provided immunity to smallpox. Although a major scientific breakthrough, the way in which this research was conducted would today be considered unethical.

The importance of performing human medical research in an ethical manner came to public attention at the end of World War II. In Nuremberg, Germany, 23 Nazi physicians and scientists were put on trial for the inhumane treatment and murder of concentration camp inmates who were used as research subjects without their consent. In addition to the convictions, which included seven defendants being condemned to death, the Nuremberg court provided guidance as to the standards for conducting human medical research. These standards, known as the Nuremberg Code, were the first attempt at establishing ethical guidelines for human research.

The World Medical Association, while meeting in Helsinki, Finland, in 1964, expanded the ethical guidelines of the Nuremberg Code and adopted the Declaration of Helsinki. These guidelines, which have been amended several times since adoption, set the stage for the implementation of IRBs.

Meanwhile, several major research trials were ongoing in the United States. Perhaps the most infamous of these was The Public Health Service Syphilis Study, also known as the Tuskegee Study of Untreated Syphilis in the Negro Male. Started in 1932, the US Public Health Service enrolled 399 illiterate and poor African American men, most of them sharecroppers from Macon County, Alabama, with the intent to study the natural history of syphilis at a time when there was no available treatment. Although penicillin became available as a treatment for syphilis in the 1940s, the men in the study were denied this treatment (without consent). This research was continued until 1972, when a whistleblower broke the news to the *Washington Star*. By that time, 128 of the men had died directly from syphilis or its related complications, 40 of their wives had become infected, and 19 of their children were born with congenital syphilis, all despite the availability of effective therapy that was not provided to the study subjects.

Due to the public outcry resulting from the Tuskegee study, Congress formed an ad hoc panel, which recommended that federal regulations be designed and implemented to protect human subjects involved in research. In 1974, Congress formed the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The charge for the National Commission was to identify basic ethical principles that underlie the conduct of research involving human subjects. These principles were subsequently published in 1979 as the Belmont Report, which is now mandatory reading for anyone involved in human subjects research. The three basic ethical principles put forth by the Belmont Report are found in Table 1.

Today, these ethical principles that protect human subjects during research have been placed into law as the Code of Federal Regulations, Title 45 Public Wel-

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*From the Department of Family Medicine, The Ohio State University.*
The Office for Human Research Protections (OHRP), housed in the US Department of Health and Human Services (DHHS), reviews, updates, and oversees these regulations. Any institution that receives money from the US government to support research must comply with these federal regulations governing the conduct of research involving human subjects. The American Educational Research Association (AERA), an international organization concerned with encouraging scholarly inquiry related to education and promoting the dissemination and practical application of its research, has adopted these principles.

**Definition of Human Subjects Research**

So, what do Jenner’s smallpox study, the Nazi medical crimes, The Public Health Service Syphilis Study, and Dr Stellar Educator’s work all have in common? They all constitute human subjects research and are subject to the same ethical principles that have just been outlined.

Federal regulations define “human subjects” as living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. “Research” is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. These, along with other definitions, are found in Table 2.

In the case presented at the beginning of this article, Dr Educator was collecting data (attitudinal changes) from the students. That may be considered standard and acceptable practice for course evaluation and improvement. However, once Dr Educator decided to share the

<table>
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<tr>
<th>Ethical Principle</th>
<th>Meaning</th>
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<tr>
<td>Respect for persons</td>
<td>Individuals should be treated as autonomous human beings. That is, they are able to make their own decisions and are free to enter into research voluntarily and with adequate information. Those who have limited autonomy (eg, diminished mental capacity, children, etc) must have extra protection. The requirements for informed consent and respect for the privacy of research subjects are derived from this principle.</td>
</tr>
<tr>
<td>Beneficence</td>
<td>“Do no harm.” Maximize possible benefits and minimize possible harms from the research. The requirements to use the best possible research design to maximize benefits and minimize harms and to ensure researchers are able to perform the procedures and to handle the risks are derived from this principle.</td>
</tr>
<tr>
<td>Justice</td>
<td>Equals ought to be treated equally. Subjects are to be treated fairly and the research designed so that the burdens and benefits are shared equitably. The requirements to select subjects equitably and to avoid exploitation of vulnerable populations or populations of convenience are derived from this principle.</td>
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<th>Table 2 Definitions*</th>
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<tr>
<td>Research</td>
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<td>Human subject</td>
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<td>Intervention</td>
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<td>Private information</td>
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<td>Minimal risk</td>
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<td>IRB approval</td>
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* Adapted from 45 CFR 46.102, Department of Health and Human Services.5
data by publication, thus making it general knowledge, the work becomes research and thus must be approved by an IRB.

The IRB—What Is It?

Federal regulations require that all research involving human subjects be reviewed and approved by a local IRB prior to conducting the research. The major purpose of the IRB is to protect the rights and welfare of the subjects involved in the research.

Each institution that accepts federal funding for research is mandated to have at least one IRB. By regulation, each IRB should consist of at least five members, both men and women, from varied professions. In addition to members who have expertise in science, the IRB should also have at least one member whose primary concerns are in nonscientific areas and one member who is not otherwise affiliated with the institution. The number and size of the IRB varies by institution. For example, The Ohio State University has four IRBs that deal with human subjects research—Behavioral and Social Sciences, Biomedical Sciences, Cancer, and Industry-sponsored, the latter of which is outsourced. Each IRB varies in size depending on the number of research protocols to be reviewed; the Biomedical Sciences IRB consists of nearly 30 members who meet for 3 hours every 2 weeks.

The IRB has authority to approve research; disapprove research; modify the research; conduct continuing reviews of the research on at least an annual basis; observe, verify, and approve any modifications to the research; observe the consent process and research procedures; and suspend or terminate approval for research. As long as federal regulations are met, each IRB may vary how it meets those standards and may even add additional procedures to meet local needs. Since IRBs vary by institution, it is essential that investigators understand the policies and procedures of their local IRB.

The research application submitted to the IRB will also vary by institution but at a minimum must contain the information contained in Table 3. The basic criteria needed for IRB approval of human subjects research is found in Table 4.

Classification of IRB Review

There are three types of IRB review procedures, and these are outlined in Table 5. Educational research usually falls into one or more of the categories listed in Table 6 and may be exempt from federal regulations and full committee IRB review. These exemptions, however, do not apply when deception of human subjects may be an element of the research, when the activity might expose the human subjects to discomfort or harassment beyond levels encountered in daily life (more than minimal risk), or when the research involves a vulnerable population such as fetuses, pregnant women, human in vitro fertilization, or individuals involuntarily confined or detained in penal institutions.

The determination of exempt status is determined by the IRB, not the individual researcher. Decision trees that may help decide whether or not a project may be exempt can be found at several Internet sites, including www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm and www.irb.arizona.edu/

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### Table 3

**Minimum Information for Human Subjects Research Application***

1. A complete description of the proposed research.
2. An analysis comparing potential risks and anticipated benefits, with assurance that risks are minimized and are reasonable in relation to the potential benefits.
3. The process and documentation of informed consent and of assent (for those who are minors or decisionally impaired).
4. An equitable selection of subjects in terms of gender, race, and ethnicity and a fair distribution of benefits among the community’s population.
5. Safeguards that protect vulnerable populations that may be susceptible to pressure to participate (eg, children, cognitively impaired, prisoners, etc).
6. Safeguards that ensure that recruitment does not invade the individuals’ privacy and confidentiality of information provided during the research.
7. A plan exists for collecting, storing, and analyzing data in a secured manner.
8. Scientifically valid research design and methods that justify subjects being exposed to the anticipated risks.

* Adapted from 45 CFR Part 46.111. Please contact the local IRB for full requirements.

### Table 4

**Basic Criteria for Institutional Review Board Approval of Human Subjects Research***

1. Risks to subjects are minimized:
   (a) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
   (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and to the advancement of knowledge.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect subjects.

* Adapted from 45 CFR Part 46.111.
If investigators believe their research will be categorized as exempt, they must submit an appropriate application requesting exempt status to the IRB, prior to initiating the research. If an exemption is granted, the investigator still must ensure that the welfare of the human subjects involved in the research is protected and that methods used and information provided to gain subjects’ consent are appropriate to the activity. The research involved in the case scenario presented at the beginning of this paper could potentially be considered exempt, depending on the type of information collected and how the students are identified.

Table 6

Educational Research Potentially Considered Exempt*

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   (a) research on regular and special education instructional strategies, or
   (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
   (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects AND
   (b) any disclosure of the human subject’s responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects; financial standing, employability, or reputation.

Note: This exemption DOES NOT APPLY to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

3. Research not exempt under #2 above, IF:
   (a) the human subjects are elected or appointed public officials or candidates for public office or:
   (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

* Adapted from 45 CFR 46.101(b)(1)-(6), Department of Health and Human Services. For the full list of potentially exempt research, see www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102.
**Informed Consent**

Even if the research is found to be exempt, subjects still must provide informed consent for their participation in the study. At a minimum, the investigator(s) must inform the subjects what they will be asked to do if they agree to participate in the research, how long the research will take, and how the confidentiality of the information they provide will be protected. The investigator(s) must also tell the subjects that their participation is voluntary, they can refuse to answer questions that they do not wish to answer, and they can refuse to participate or they can withdraw at any time without penalty or repercussion. Finally, subjects should be given the name and phone number of the investigator(s) should they have further questions about the study.

Sometimes the IRB may waive the requirement for informed consent (such as when the research involves a retrospective chart review or making observations only) or may grant a waiver of written consent. Normally these waivers may be granted for research that involves no more than minimal risk to subjects, the waiver will not adversely affect the rights and welfare of the subjects, the research could not otherwise be practically carried out without the waiver, and, when appropriate, subjects will be provided with additional pertinent information after participation.

**Students as Research Subjects**

Health professions students and residents traditionally have served as subjects for biomedical and behavioral research. Learners involved as subjects in a faculty member’s research project are considered a “vulnerable population” because they may perceive that their grades, or faculty member’s favor, might be dependent on their participation in the research. Ethical standards of research dictate that consent to participate must be voluntary and that subjects have the right to choose to take part in research projects. Indeed, federal regulations (45 CFR 46.116) state, “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.”

Learners receiving grades and recommendation letters from researchers may feel, rightly or wrongly, that they are being coerced to participate in the research. Also, most IRBs will not allow learners to participate as subjects in their faculty’s clinical research if the study poses greater than minimal risk to the learners. Exceptions are allowed for those who may derive direct health benefits and are determined on a case-by-case basis.

The faculty member needs to take extra precautions to ensure that the learners are not coerced or unduly influenced to participate. No matter how well intentioned the faculty member is, students may feel obligated to participate, believing that failure to do so will negatively influence their grades and the attitude of the faculty member (and perhaps other students) toward them. Students need to be informed, in writing, that their participation is entirely voluntary and that they have the right to withdraw from an ongoing project at any time without prejudice or penalty. If extra credit for participation is offered, students must be offered a

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**Table 7**

An Example of Informed Consent to Use Evaluation Data

The Ohio Center of Excellence in Education for Bioterrorism Preparedness and Response, a collaborative of health care educators funded by the Health Resources and Services Administration, needs your help. Our Center is responsible for integrating training for health care professionals on being prepared in the event of a bioterrorist attack. As part of this task, we designed this presentation, “An Introduction to the Threat of Bioterrorism—What Every Health Care Provider Should Know.”

We need your feedback on whether this presentation was useful to you in learning about the potential bioterrorism threat to you and your patients. We also would like to gather some information from you as to whether or not you feel that the “war on terror” has impacted you or your family or friends.

We may want to eventually publish some things about this presentation. To do so, we ask your permission to use your answers as part of the report. First, this evaluation is ANONYMOUS, meaning that we do not want your name on this form. Also, your answers will be grouped with others who are completing this evaluation, so there will be no way to link your answers to you. This evaluation form should take no more than 10 minutes to complete. Also, allowing us to use this information is entirely voluntary. The first question of the evaluation form asks whether or not we can use this information, in aggregate, for future publication. If you do not want us to use your answers, please mark the “no” box. By doing so, you will in no way be penalized as a student for not wanting us to use your answers. Remember, we wouldn’t be able to do this anyway since this is an anonymous evaluation. Even if you do not give us permission to use your answers, in the case we want to publish the results, we still want you to complete the evaluation so that we can make improvements or adjustments as needed.

Finally, to determine whether or not this presentation was effective, we would like to ask you questions before and after the presentation. To be able to compare these results, we ask you to select a four-digit number (avoid 1-2-3-4) that is meaningful to you that you can remember, and put this number on the evaluation. By doing this, you will allow this evaluation to remain anonymous. Also, to help you remember, please write the number here and then remove this front page and keep it for your later use.

Your four-digit number: ___ ___ ___ ___

Should you have any questions about the conduct of this evaluation or study, please contact Fred Miser, MD, MA, at 614-293-2655 or miser.6@osu.edu.
reasonably alternative to participation, which should be equal in extra-credit value and approximately equivalent in both time and effort.

There are two different scenarios in which an investigator may wish to use students in a class as research subjects. First, the research is being done to evaluate the effectiveness of the instruction and/or curriculum, with the intent to eventually present or publish the results. For example, an instructor may use different teaching methods (e.g., lecture versus small-group discussion) to teach subjects and wants to compare evaluations between the different methods. Although this type of data collection is considered to be standard educational practice, the fact that it involves human subjects mandates that a Request for Exemption be submitted to the IRB before the study is undertaken.

The second scenario is that the students themselves, not the curriculum, are the focus of inquiry. For example, an investigator may wish to compare the attitudes between medical and nursing students toward treating patients who have a particular disease. If the survey is done anonymously, a Request for Exemption submitted to the IRB may be the appropriate step. However, if the study involves a face-to-face interview, or anonymity cannot otherwise be guaranteed, or if any disclosure of the responses could reasonably place the student at risk of criminal or civil liability or be damaging to the student—either their financial standing, employability (which might be influenced by grades or recommendation letters), or reputation—the research is not exempt and must be submitted to the IRB for either full committee or expedited review. The investigator must take great care to develop the consent and research procedures in such a way to assure that student participation is voluntary.

In the case of a course evaluation, the results of which may eventually be submitted for publication, a cover sheet containing a recruitment script must inform the students that their answers may be used as part of a research project, that their participation is entirely voluntary, and that if they choose not to participate, their grades will not be influenced. The best way to assure this to be the case is to make the evaluation anonymous. If one wants to do a pre- and post-course evaluation, then have the students come up with their own unique, memorable four-digit number that they put on the forms. If demographic data of the subjects are required, collect it in such a manner that individuals cannot be personally identified. For example, instead of asking for their birth date, ask for their age in a range category (e.g., 20–24 years, etc). An example of a cover sheet providing informed consent for an evaluation is found in Table 7. Other examples can be found at the Web site of the Indiana University Office of the Vice President for Research (www.indiana.edu/~resrisk/exhibita.html). Site visited November 10, 2004.

Final Recommendations

Hopefully by now you understand how educational research using learners is held to the same ethical standards required of the more biomedical type of research. If you even consider presenting or publishing the results of an educational intervention (e.g., a new course, a novel way to teach a course, etc), I offer the following suggestions.

First, as you are planning the educational intervention, be proactive about getting IRB approval, even if you never pursue publication of the results. By considering this intervention as research, you will be able to perhaps ask better questions in the evaluation and ask them in a way that protects the identity of the learners. Input by the IRB could also potentially strengthen the results of the study, which will enhance the chances of subsequent publication.

Second, get to know your IRB and the policies that they follow. No IRB is the same, and although all must follow the federal regulations outlined in this paper, each will have its own unique requirements. Talk to the IRB chair about how educational research is handled at your institution, and become familiar with the required forms and application process.

Finally, a modification of an old Army saying is, “Prior planning prevents poor performance.” Planning your educational intervention as if you were going to publish the results will only enhance the quality of your intervention and its evaluation. For those of you who want to learn more about human subjects research, an excellent on-line course can be found at www.citiprogram.org (site visited November 10, 2004).

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REFERENCES