

## Curriculum and Case Notes

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Submissions to Curriculum and Case Notes should be sent to Matthew Auer, Indiana University, School of Public & Environmental Affairs, 1315 E. 10th Street, Bloomington, IN 47405-1701.

### SHOULD CAPSTONE COURSE ACTIVITIES UNDERGO HUMAN SUBJECTS REVIEW?

Jan Blustein

Like many schools of public policy and management, New York University's Wagner School offers a capstone course in which teams of MPA students provide consultation to client organizations. This year, as we began to assign students to teams, some members of the faculty sounded an alarm. Several of the projects might involve interviewing service recipients about sensitive issues. Other projects would give teams access to confidential information. Faculty members experienced with our university human subjects review board knew that such projects, were they to be undertaken in a research context, would require lengthy and cumbersome review.

Did the capstone projects need to go through the human subjects review process? If the answer was yes, our program would come to a grinding halt, given the open-endedness of the capstone assignments and the bureaucratic nature of the committee application and approval process.

As Wagner's incoming representative to the university's human subjects review board—commonly known as the Institutional Review Board, or IRB—I had a particular interest in the matter. My sense was that the alarm was probably unnecessary. The IRB, after all, had never approached us about our capstone activities, and there had been plenty of outreach from them with respect to reviewing our funded research projects. The notion of an outside board's overseeing professional education seemed intrusive and unnecessary. The question, however, had been raised. I knew that the human subjects review board was constituted under federal regulation, and was subject to penalties and sanctions. Since I would soon join the board, I needed to know more.

One of the first things I did was to post a query on the APPAM listserv. I found that we were not alone in our concerns. Fifteen people responded, and their advice was mixed. One urged that we “err on the side of caution” and submit the capstone projects for review. Another advised that capstone work is a “gray area” and that “most people . . . [k]eep the survey parts below administrators’ radar screens.” Still another noted that the capstone would automatically qualify for an exemption from board review at his institution, since it is offered for academic credit. Finally, several respondents reported having standing arrangements with their university IRB to review such projects internally (within their schools), allowing the projects to move forward in a timely fashion. This range of responses served as an interesting base from which to explore the issues. In this Curriculum Note, I report on what I have learned since then.

### THE WAGNER SCHOOL CAPSTONE

But let me begin by describing our capstone program, which is the major “clinical rotation” in our curriculum. The experience is essential, because it affords students the opportunity to translate classroom learning into professional practice:

The Wagner School prepares students for the real—sometimes messy, always complex—world of public service. To achieve this mission, we know it is essential to synthesize theory with practical realities by taking students beyond the classroom to confront and solve real problems facing real organizations. We firmly believe that this exposure is vital to our students’ ability to translate academic study into top quality professional skills.

The Capstone Program is a consulting resource for nonprofit, community and health organizations, international NGOs, and government agencies. The Program brings together teams of graduate students with client organizations to address complex challenges and identify new opportunities for their clients.<sup>1</sup>

Historically, our teams have performed superbly, as evidenced by the keen competition for capstone help among client organizations in New York City and beyond. Members of client organizations commit to meeting regularly with a team, first to frame the problem at hand, and to provide critical feedback as the need arises. Faculty members who guide and support student teams are responsible for ensuring that the teams conduct their activities in an appropriate, professional, and timely fashion. Most of the faculty are managers with many years’ experience in the public and non-profit sectors; others are full-time faculty at the school.

The capstone is a formal course, and students are assigned grades and receive academic credit upon successful completion. For most students receiving the MPA, completion of the capstone is a requirement for graduation. In sum, our capstone shares many features with those offered in other schools of public policy and management (Allard and Straussman, 2003; Flynn, Sandfort, and Seldin, 2001; Vining and Weimer, 2002).

<sup>1</sup> “The Capstone Program.” Description and FAQs on the program, for circulation to prospective client organizations. (Obtained from C. Sherwin September 10, 2003.)

## **CAPSTONE IN A WIDER CONTEXT: CLINICAL EDUCATION FOR PROFESSIONAL STUDENTS**

It is noteworthy that the capstone also shares features with the clinical education received by advanced students in fields other than public policy and management. At some point in that education—after absorbing much of the “book learning,” but before being certified as full members—fledgling professionals learn by doing. For example, reviewing professional education at NYU, I found that:

- The Business School runs a consulting firm staffed by students. Over the past 20 years, student teams have provided analysis and advice to hundreds of organizations, both for-profit and non-profit.<sup>2</sup>
- The Law School runs an extensive clinical program (Public Policy Advocacy, Capital Defense, Civil Legal Services, Civil Rights, Community Economic Development, Family Defense, Federal Defense, Immigrant Rights, and Juvenile Defense, among others) in which students interview clients as to very intimate details of their life circumstances and represent clients in court proceedings as well as administrative tribunals.<sup>3</sup>
- The Medical, Dental, and Nursing schools provide numerous rotations during which students provide medical services to patients.

It bears emphasis that these training experiences involve contact with people, some of whom are either disadvantaged, vulnerable, or both. Students participating in these programs often ask probing questions of the sort that would be subject to close IRB review, were the intent of the questioning to perform research. Moreover, the training experience gives students access to information (written and electronic) that is sensitive and could cause harm if publicly disclosed. Such access would also draw careful IRB attention in the research context.

But none of NYU’s professional schools asks the IRB to review their clinical training, nor have I heard of our already-overworked IRB suggesting that they should. Rather, the schools take the approach historically used in the professions: Senior professionals well versed in the ethical underpinnings of the field supervise clinical training. These senior individuals ensure (and are accountable for) the work’s being conducted in an ethical, sensitive, and appropriate fashion. For example, full-fledged physicians review and co-sign patient orders written by medical students in training. While legal as well as ethical concerns undoubtedly drive this practice, it signals the extent to which the profession holds senior members responsible for the correct activities of those who are most junior.

## **THE NATIONAL/FEDERAL PERSPECTIVE**

It is worth noting that there is currently a great deal of discussion at the national level about human subjects protection and the role of the IRB. That debate has engaged researchers, universities, think tanks, federal regulators, professional societies (including the AAUP and professional associations connected with the

<sup>2</sup> Per Professor Charles Forbrun, Stern School of Business, New York University, in e-mail to J. Blustein. The program is briefly described at <<http://pages.stern.nyu.edu/~cforbrun/Fundamentals/ug-syllabus1.html>>.

<sup>3</sup> Per Ellen Schall, Dean of the Wagner School and Life Trustee, NYU Law School, personal communication to J. Blustein. The program is described at <<http://www.law.nyu.edu/clinics/>>.

various disciplines), and other stakeholders. A brief discussion of the issues, and Internet links to the positions of key players, can be found in an excellent review by Singer and Levine (2003). As the authors report, there are forces propelling both expansion and contraction of the IRB sphere. On one hand, there is an impulse for increased IRB stringency, stemming from the recent well-publicized deaths of research subjects in medical clinical trials at high-profile universities, and the consequent federal shutdown of research at those institutions. On the other hand, there is also a significant movement to restrain the reach of IRBs with respect to social and behavioral research—or perhaps more accurately, to modify or clarify the way in which the federal regulations apply to that research. This movement has been led by social researchers who believe that the longstanding regulations reflect a medical model of research that is ill-suited and even detrimental to the investigation of social phenomena. A key goal is to get federal regulators to be more explicit as to how concepts like “minimal risk” and “informed consent” apply in social research. (See, for example, Sieber, Plattner, and Rubin, 2002; also Gunsalus, 2003.) Regulatory change has been slow, however, and, pending action by the federal government through its Office of Human Research Protections, housed in the Department of Health and Human Services, institutions are likely to remain risk averse in their approach to human subjects issues.

#### SHOULD OUR CAPSTONE COURSE BE SUBJECT TO IRB REVIEW?

In deciding whether the capstone projects needed to undergo IRB review, a key question was whether the work constituted “research” as defined in the federal regulations. The Code of Federal Regulations (CFR) 45A (also known as the “Common Rule”) is the Federal government’s regulatory statement of IRB scope and activity. It clearly states that IRB oversight applies only to research, and defines research as follows:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.<sup>4</sup>

A more explicit statement can be found in the Belmont Report, the major declaration of human subjects policy that has guided federal activity in this area for the past quarter century:

. . . the term “research” designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.<sup>5</sup>

It is notable that, in both cases, whether an activity constitutes research cannot be determined by a description of the activity itself. (For example, “asking 100 people sensitive questions” might be “research”—but it could be “gossip”!) At issue in

<sup>4</sup> CFR 45A 46§102(d).

<sup>5</sup> Belmont Report, Part A.

determining whether something is research is the intent with which the activity is carried out, and whether it is performed systematically. Those activities designed and carried out to contribute to generalizable knowledge are research. Moreover, to the extent that such activities are systematic, and embedded in theories, principles, and protocols, they are more likely to be “research.”

It bears emphasis that research activities are thus held to a much higher standard than everyday activities. In everyday life we can probe, embarrass, and betray with impunity (more or less; our behavior is “policed” by informal social norms). But in our research lives we are formally regulated. The Common Rule draws the line between everyday life and research life primarily by invoking the notion of generalizability. The link between research, generalizability, and ethical accountability is an interesting one, and it makes sense in historical context. Briefly, the Belmont Report was written, and the Common Rule was formulated, in the wake of public disclosure of abuses of science, including the infamous Tuskegee Syphilis Study. In those abuses, vulnerable people became research subjects—and were exposed to considerable risk—with the (ostensible) goal of enhancing general knowledge. As the Belmont Commissioners noted, this raised a question of distributive justice, namely why some individuals should bear disproportionate risk for the production of knowledge for all. Their answer was that if all are to benefit, all should bear risk—or, at least, those who are most vulnerable should not bear disproportionate risk. Thus, when generalizable knowledge is being produced (*viz.*, in research), extra protections must be in place to ensure the highest standard of conduct.<sup>6</sup>

With this in mind, I consulted with my colleagues and reviewed whether capstone activities constitute research, as defined in the regulations. My conclusion was that they do not. First, students undertake the activities with the intent of assisting the client organization, and not with the goal of contributing to generalizable knowledge. While teams may observe, interview, or even formally survey individuals, their findings are for the client audience, and not for general consumption.<sup>7</sup> Second, the process by which the capstone teams work is not systematic, scientific, or protocol-driven—it is highly pragmatic, inherently “messy,” non-protocol-driven, and subject to frequent revision. It is not even clear to me that capstone projects could be prospectively presented in the detailed format that is used by the typical IRB.

Before moving on, I would note an additional consideration that argues for capstone projects’ being beyond IRB purview. That consideration is equity. If professional training for management and policy students is “research” and thus subject to IRB review, then the same oversight should apply to the training of students in professions like business, law, and medicine.

<sup>6</sup> Of course, this is a highly simplified account. For a nuanced discussion of the principles of research ethics in the medical context, see Beauchamp et al. (1982). Early tensions between the medical model and social science research are reflected in Rivlin and Timpane (1975).

<sup>7</sup> Even if the capstone findings were occasionally published, I would argue that this would not make the work “research,” if the work was *not undertaken with the intention* to enhance generalizable knowledge. Such publications (if there were any) would probably be most analogous to the “Case Reports” that appear in medical journals. In “Case Reports,” patients with unusual disease manifestations are described in order to enhance general medical awareness of the exotic. But physicians publishing case reports usually undertake the care of such patients in a clinical spirit. As a practical matter, the issue almost never arises in the capstones. Most projects are completed in the final few weeks before graduation. At that juncture, publication is typically not a priority for our students.

## HOW TO ENSURE ETHICAL CONDUCT IN THE CAPSTONE?

Having thought this through with the help of colleagues, I presented my findings to an officer of the university IRB. She concurred that the need to seek review by her board is circumscribed by intent, generalizability, and scientific rigor, as outlined in the regulations. She pointed out, however, that while her board may not be the appropriate means through which to ensure the ethical conduct of professional education, this does not mean that students should be blind to the important issues typically addressed by such boards. These issues include informed consent, confidentiality, assurances that services will not be withheld if service recipients prefer not to participate in a survey, and so on. Moreover, she argued, our students should be aware of the principles of autonomy, justice, and beneficence, as articulated by the Belmont commissioners.

In sharing this outcome with colleagues, I was reassured to note that we already have in place two important mechanisms to ensure ethical conduct. The first is the involvement of our capstone faculty. Experienced individuals versed in the ethical foundations of professional practice oversee the work of each of our teams. Second, client organizations have a stake in, and continue to be involved in, the teams' activities, as those activities evolve. In our experience, client organizations are generally sensitive to ethical issues, such as privacy and confidentiality, and are also cognizant of their related legal responsibilities.

While we feel that we are on firm ground, we have agreed that we would like to do better. We are developing a checklist of ethical issues to distribute to capstone faculty as they begin to supervise next year's projects. We have also identified a group of individuals who are familiar with human subjects issues and the Belmont framework. This group will be available for ad hoc consultation to the teams. We will see how this works next year. I will hope to report to you again, as developments unfold.

I am grateful to John Billings, Carol Sherwin, and Ellen Schall for their interest and assistance. I would also like to thank those members of the APPAM listserv who responded to my initial enquiry on this topic. The opinions expressed here are my own.

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**MATCHING STUDENTS TO PROJECT GROUPS  
USING THE "ELIMINATION AUCTION" PROGRAM**

**Eugene Bardach**

I teach a semester-long workshop class that sends teams of three to five students into the field to do policy analysis projects for real clients. I spend several weeks before the class begins assembling plausible projects. I present a menu of some 30 projects to a class of about 75 students. The problem is to assemble some 20 to 23 project teams of three to five persons in such a way as to maximize aggregate utility.

When the class was half the current size, I could do the matching by hand. But the task is now much too complex. Fortunately, a Goldman School alumnus from the class of 1997, Brian Hardy, has developed a computer program to perform 95 percent of the matching. He calls it an "Elimination Auction."

Students express their individual preferences by dividing 1000 points among their four favorite project topics. They are limited to 700 points maximum for any single project, and 100 points minimum. They are permitted to designate up to three other students whom they wish to avoid. The program is Web-based, and students can enter their preferences in less than two minutes by accessing the Web site.

Once all the student preferences have been logged in, I run the program. I usually set the group size parameters for minimum three and maximum four. A click of the mouse spins students into provisional project groups. Projects that do not attract much student interest disappear in the first run or in subsequent runs. Some 25 percent of projects from the menu die in this fashion. Student points originally assigned to the vanished groups are reassigned automatically to the students' remaining choices. The program iterates until the sum of all student points is maximized. Usually a few of the students are not assigned, and these must be added to groups by hand. These "leftovers" typically occur because the students have chosen two or more vanished projects and/or because they are either avoiding others or are being avoided.

Occasionally I wish to preserve certain projects. Some I regard as excellent learning opportunities, and some I preserve for clients who have a special claim on getting the services of our students. The program's user interface easily permits the user to "protect" or to drop certain projects and to drop from subsequent runs student members of project groups regarded as "done." It takes a little experimentation

with different group size parameters, and with protecting and deactivating combinations of students and projects, to get a reasonable result. The whole process takes an hour or two. When I did the matching by hand for half the numbers of projects and of students, it took four to five hours. With the current numbers, I could imagine spending ten hours and not getting as good a result.

And one further benefit: The mindlessness of the computer program probably seems fairer to the students than the judiciousness of the professor.

For further information contact Brian Hardy at <bhardy@rdsinternational.com>.

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