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Administrator Beware: External Supervision Issues Regarding Human-Subjects Based Research

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ONGOING changes in federal, state, and campus regulatory environments regarding human subjects based research compel speech communication administrators to take a more active role in ensuring that area faculty and graduate students are aware of current regulations and guidelines governing their related research activities. Speech communication matters and doctoral students involved with human subjects-based research normally are focused on sorting out basic experimental design and/or data collection and analysis issues pertaining to thesis projects and initial convention paper and journal article submissions. Awareness of emerging regulatory issues concerning how their human subjects-based research is conducted may not be adequately addressed in graduate level "design" classes. Correspondingly, speech communication faculty involved with human subjects-based research may not be aware of recent external supervision issues generated by dynamic federal, state, and campus regulatory activity.

On July 12, 1974, the National Research Act (Pub. L. 93-348) resulted in the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission subsequently identified ethical principles and guidelines for the protection of human subjects (see *The Belmont Report*, April 18, 1979). Since the release of *The Belmont Report* both the *Code of Federal Regulations* ("Public Welfare," Title 45, 46.101, revised as of October 1, 1992) and the codes of regulations of various states (e.g., *Code of Virginia* [1950], Title 32.1) have comprehensively detailed specific requirements for ensuring ethically responsible research involving human subjects. Also detailed in both the federal and various state codes of regulations are guidelines and regulations pertaining to the

establishment of institutional review boards charged with overseeing in-house human subjects based research activity. Each institutional review board may generate locally based research guidelines that may be even more stringent than those detailed in both the federal and state codes.

The following is a hypothetical example of a Virginia university institutional review board for the protection of human subjects communicating to their provost, a speech communication faculty member, and the head of the speech communication department the board's concerns about a research project that the faculty member is conducting. The case illustrates a number of current issues that speech communication administrators, departmental faculty, and graduate students need to consider as their human subjects based research becomes increasingly overseen by some external supervisory agent or agency.

March 15, 1995

TO: Dr. XYZ, Professor, Department of Speech Communication
 Dr. ABC, Provost
 Dr. DEF, Head, Speech Communication Department

FROM: Hypothetical University Review Board for the Protection of Human
 Subjects (RBPHS)

SUBJECT: RBPHS Recommendation Regarding Professor XYZ's Research
 Project— "The Impact of Interactive Video Instruction on Introductory
 Public Speaking Students' Communication Apprehension Levels"

The RBPHS anonymously received a copy of a self-report instrument ["Personal Report of Public Speaking Apprehension"] that students who are currently enrolled in Introductory Public Speaking 101 are being asked to respond to by Professor XYZ (Director of Public Speaking 101). The cover sheet attached to the instrument indicates that only 101 students enrolled in the nine sections using computer-assisted instruction (CAI) should respond to this posttest administration of the instrument. Although the RBPHS supports research being generated from the new interactive video instruction (IVI) lab funded by a recent in-house President's Instructional Resources Development Grant, we have some concerns. They are as follows:

- (1) Our committee must act in a manner consistent with our charge [*see Code of Federal Regulations - Public Welfare - Title 45 & Code of Virginia (1950), title 32.1*] as detailed locally in our *Faculty Handbook* (revised 1993). The RBPHS: (a) reviews and approves research activities which involve human subjects. (b) reports to the Provost (IV, p. 11).
- (2) The instructions attached to the instrument state, "...at the beginning of the spring semester you were asked to complete a questionnaire for a study examining the impact of interactive video instruction on student public speaking apprehension levels. In order to complete this study the questionnaire must also be administered at the end of the semester. Please provide your responses to both the Personal Data Survey and the Personal Report of Public Speaking Apprehension..."

A copy of this study's data collection instrument and details regarding corresponding data collection procedures were not submitted to our committee for review. The "Personal Data" section of the instrument requests that each student provide her/his social security number and information pertaining to race, sex, age, employment status, etc.

The *RBPHS Guidelines* (Revised 1992) distributed to all members of the instructional faculty and administrators (copy enclosed) address that:

Faculty research...done in any way in connection with the college, when it involves the use of human subjects, should be cleared by the RBPHS. Submission of such research to the RBPHS should include a written narrative that addresses the guidelines outlined by the RBPHS.

"*Confidentiality and anonymity.* Procedures for maintaining both anonymity and confidentiality must be outlined in detail."

"*Freedom from coercion and exploitation.* Especially when the researcher may be a teacher or supervisor of the subject, the subject needs to know that participation or nonparticipation in the research will not effect her/his class grade...The subject must also be assured that she/he can withdraw from the research at any time. Participation...cannot be made a class/job requirement."

Although this survey is certainly innocuous (the instrument does not solicit information that could place the subjects at risk of any criminal or civil liability, and does not deal with sensitive aspects of the subjects' own behavior) the RBPHS is concerned that information is being recorded in such a manner that subjects can be identified directly through the social security identifier. Was any assurance of anonymity given to survey respondents and was it stressed that their participation in this study was voluntary? [The nature of this investigation does not engender RBPHS concerns about other guidelines related issues (e.g., informed consent, protection from physical and mental stress, post research debriefings, etc.).]

On March 8, Dr. GHI of the Virginia Department of Education [804 225-2762] supported in a telephone conversation that the data collection procedures used in this study were in violation of *existing* state regulations pertaining to both student learning outcomes assessments and survey research. The existing state regulations [Title 32.1, *Code of Virginia* (1950)] detail that:

32.1-162.17. Exemptions (pp. 489-490)

2. Research or student learning outcomes assessments conducted in educational settings involving regular or special education instructional strategies, the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods, or the use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, *if the data from such tests are recorded in a manner so that the subjects cannot be identified, directly or through identifiers linked to the subjects.*
3. Research involving survey or interview procedures *unless responses are recorded in such a manner that the subjects can be identified, directly or through identifiers linked to the subjects* and either (i) the subjects' responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability

or be damaging to the subjects' financial standing or employability...

The Virginia regulations concerning research involving survey procedures are in concert with established federal guidelines (see *Code of Federal Regulations - Public Welfare Title 45, 46.101*).

Dr. GHI indicated that the good intentions of the researcher are not relevant to the data collected in the "IVI" study. The regulations apply to the criterion of "fugitive data." If the data collected became known outside the research [accidentally, etc.] would the subjects be at risk? JKL, Agent with the United States Secret Service [1-441-3200] commented on the risks associated with the use of the social security identifier. He suggested that the Secret Service frequently investigates numerous crimes made possible through the use of real social security numbers—fraudulent acquisition of credit cards; cashing of government checks; acquisition of false identification documents; etc. Agent JKL indicated that college students are often the subjects of investigations concerning improper and illegal use of social security numbers. Once a victim's social security number is used in the fraudulent acquisition of a credit card the individual can not correct the damage done to her/his credit rating expediently. Agent JKL further indicated that savvy computer hackers would have little difficulty in discovering the names and addresses of individuals whose social security numbers were acquired.

The concern about the use of the social security identifier may seem an overly cautious reaction considering its frequent appearance on many driver's licenses, personal checks, etc. The RBPHS believes, however, that procedures for maintaining the anonymity and confidentiality of our students' responses to even the most innocuous survey instruments must be followed.

In a February 2, 1994 memo ["Human Subjects Research Done With Students In The Public Schools Of Virginia"] distributed by Provost ABC to HU's academic deans and the chair of the RBPHS—proposed revisions of *Code of Virginia* regulations governing such research were detailed. The January 24, 1994 draft of the proposed regulations attached to the Provost's memo indicated that survey research would be exempt "unless responses are recorded in such a manner that the students can be identified, directly or through identifiers linked to the subjects" (p. 7, no. 2). The same criterion was presented for research regarding learning outcomes assessments. The new language proposed for the *Code of Virginia* eliminates any potential exceptions:

Because the data of the study regarding interactive video instruction (IVI) were collected through the use of the social security identifier for student participants the RBPHS recommends that the original, unduplicated pre and posttest data collected be turned over to our committee for destruction and that no public dissemination of related information be permitted. A cleaner data collection procedure could easily be distributed to students during another academic term.

The RBPHS has followed federal guidelines, state regulations, and university policy with regard to this matter.

State regulations (32.1-162.19) address that:

B. No human research shall be conducted or authorized by such institution or agency unless the committee has reviewed and approved the proposed human research project... (p. 491).

As stated earlier, our *Faculty Handbook* (revised 1993) details that the RBPHS:

- a) reviews and approves research activities which involve human subjects
- b) reports to the Provost (IV, p. 11).

Further, as stated above the *RBPHS Guidelines* (Revised 1992) distributed to all members of the instructional faculty and administrators address that:

Faculty research...done in any way in connection with the college, when it involves the use of human subjects, should be cleared by the RBPHS. Submission of such research to the RBPHS should include a written narrative that addresses the guidelines outlined by the RBPHS.

No research proposal regarding the “IVI” study was ever submitted to the RBPHS to review. The instructions attached to the IVI study instruments indicate that pretest data have already been collected and posttest data have been or are being collected currently [without RBPHS approval].

Federal guidelines detail that:

An IRB (institutional review board) shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements...Any statement or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. (See 46.113).

Federal guidelines detail that reviews of proposed research may take place at convened meetings at which a majority of the members of the IRB are present. All five RBPHS committee members were present at our March 14 meeting and voted unanimously to disapprove this project “after-the-fact” [data having already been collected] in accord with its charge to protect human subjects and the university. (See 46.108).

The federal guidelines further detail that:

An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. (See 46.109).

Dr. XYZ has requested that he be permitted to meet with the RBPHS. Based on the information detailed in this letter, at this time, before we venture on a data salvage expedition, it would seem appropriate for the provost to review the RBPHS’s disapproval of the unauthorized research that has been conducted. Additionally, before any formal meeting between the committee and Dr. XYZ is scheduled, established university policy should be followed regarding the formal submission of a research proposal to the committee that includes a written narrative addressing the guidelines outlined by the RBPHS. (See *RBPHS Guidelines [Revised 1992]*.)

The fictitious memo detailed above is based on the actual guidelines and regulations (and current proposed regulatory changes) of the *Code of Federal Regulations, Code of Virginia, and Guidelines (Revised 1992)* of the Review Board for the Protection of Human Subjects—

Christopher Newport University. The use of the social security identifier as a means for correlating subjects' pre and posttest survey responses was selected to illustrate how easy it can be for a researcher to inadvertently err. As speech communication faculty and graduate student human subjects based research becomes increasingly overseen by some external supervisory agent or agency, it is essential for awareness of the current regulatory environment to guide their research designs. Administrators can proactively ensure that guidelines and regulations concerning the protection of human subjects—as translated into the texts of current federal and state codes and corresponding university IRB applications—will be an integral part of the research agenda of area faculty and graduate students.

REFERENCES AND NOTES

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Faculty Handbook (Revised 1993). Christopher Newport University, Newport News, Virginia 23606-2998.

Guidelines (Revised 1992). Review Board for the Protection of Human Subjects, Christopher Newport University, Newport News, Virginia 23606-2998.

The Belmont Report (April 18, 1979). Department of Health, Education, and Welfare.