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H. James Williams, Ph.D., Dean, Seidman College of Business
CC: Priscilla Kimboko, Ph.D., Dean, Office of Graduate Studies & Grants Administration
From: Paul J. Reitemeier, Ph.D., Chair, Human Research Review Committee

Date: December 10, 2008

Re: Clarification re: student activities that require HRRC review and approval

A complaint was recently received by our office pertaining to a GVSU student led survey in the community that had not been properly reviewed and approved by the HRRC. I discussed the matter with the affected faculty members and gained a better understanding of their confusions about the regulatory requirements. This memorandum may clarify similar confusions.

By federal law, all human subjects research must be approved by the HRRC prior to initial contact with research subjects. The HRRC is aware that many GVSU students regularly engage in course activities involving surveys, interviews, and other forms of data collection from living persons. Some of these activities meet the definition of research in the federal regulations but many do not. HRRC approval involves filing protocol review forms, authorizations documents, consent forms, etc., waiting for the review process and finally receiving determination letters which sometimes request additional information or modifications in planned procedures. This process sometimes requires more time to complete than is available in a single academic term. However, forethought and planning by researchers may significantly enhance timely review.

In the attached 2 pages I describe three types of common class activities and interpret each one as either (i) research requiring HRRC review, (ii) research not requiring HRRC review, or (iii) not human subjects research. The HRRC has concurred with these interpretations, and authorized their communication to you as clarification of the its position on required review of research activities involving living persons.

I request that you to share this document with all unit heads and faculty in your colleges to assist their understanding of when academic course related activities need HRRC approval and when they do not. We are available to answer any questions and to meet with individual or groups of faculty for more specific assistance. The HRRC office is open Monday through Thursday, 8:00-4:30.

Code of Federal Regulations Definitions

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. **45 CFR 46.102(d)**

Human subject means a living individual 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*. **45 CFR 46.102(f)**

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Case 1. Students study, discuss and then develop a list of retail salesperson techniques. They design a survey of professional salespeople re: their beliefs about how effective each technique has been for them personally, and why. The survey participants are selected solely by being known personally or conveniently by the class members. No attempt is made to determine a sample size for statistical significance, nor to stratify or select participants based on any demographic feature other than adult status. The results of the survey are presented in but not discussed outside of the class meetings, and the students' work is a graded exercise.

Interpretation. This activity is not a systematic investigation in any meaningful sense. The selection of participants is not random but haphazard, it is underpowered for statistical significance, and there is no attempt to generalize the results beyond the sample of respondents collected. The activity is not research as defined by the federal regulations, and does not require HRRC review or approval.

Case 2. An automobile dealership wishes to learn about its customers' perceptions of the company operations and service. The company contracts (for no compensation) a GVSU marketing class to survey a random sample of its current and past customers. The company provides customer contact information to the faculty member and students. Customers who agree to participate are surveyed and their perceptions are recorded anonymously and then

analyzed by the students. The results are provided to the company leadership, and discussed in class as part of the course learning objectives. No publications or other public disclosure of the results are planned or conducted.

Interpretation. The survey participants are a random sample of the larger target population (company's entire customer base). The survey results are generalizable only in the sense of being representative of the rest of that population. However, the participants' perceptions do not contribute to "generalizable knowledge" in the relevant sense, i.e. re: the participant's experience with any other company. As such, the collected data should be considered part of internal quality assessment rather than human subjects research. The project therefore does not meet the relevant definition of research.

Case 3. Class project similar to case 2, but the student survey now seeks participants' perceptions about operations and services of one or more of ten identified companies, e.g. local automobile dealerships. The survey participants are randomly selected from individuals listed on a public database of recent automobile license purchasers that reside in a predefined set of zip codes. Survey participants' perceptions are voluntary and anonymous, and after analysis the results are shared only with the contracting company, and discussed in class. Two of the students present their results in a poster format on Student Scholarship Day.

Interpretation. In this case, the activity is human subjects research, but it is exempt from the regulations under exemption category 45 CFR 46.101(b)(2). The survey results could contribute to generalizable knowledge in the relevant sense intended by the regulations. They represent the perceptions of a cross section of the recent automobile buying public about their buying experiences. The study results, therefore, presumably could be extended to the larger automobile buying public. Moreover, selected survey results are made publically available to anyone passing through the poster sections of SSD a few months later.

Note: determining that the activity is research is the faculty member's responsibility, but determining that it is *exempt* research can only be made by the HRRC.

Addendum: Case 3 is the only class activity that requires HRRC review and approval in the examples above. Since it is a common research technique that may be repeated in future semesters, the protocol could be drafted in a generic format by the faculty member and re-used each semester. To enable a speedy review process the faculty member could submit the protocol to the HRRC for review, and if it is judged by the HRRC to qualify under one of the six exemption categories in the federal regulations, and the only missing element is the set of specific survey or interview questions, the project can receive provisional approval prior to the start of the term. When the list of survey or interview questions is finally available, it could be submitted as a completion of the application, and quickly reviewed and approved as an exempt research activity. Typically this final part of the review and approval can be completed in 1-2 days.