

What Institutional Researchers at Technical and Community Colleges Need to Know About IRBs, FERPA, and the Protection of Human Participants in Research

Viktor Brenner, Ph.D.
Waukesha County Technical College

Unlike in the past, research occurs at technical and community colleges today, but few have procedures to manage the potential liability that comes with it. Four-year colleges use Institutional Review Boards (IRBs) for this; this is cost-prohibitive for most two-year schools, but it might be sufficient to apply IRB procedures using local resources. Viewing research projects as an IRB would also help maintain compliance with federal and state statutes such as FERPA. Institutional Research projects themselves may not need IRB approval but still introduce a liability risk—loss of confidentiality especially—and we should adopt the perspective of an IRB when designing projects.

Once upon a time, research occurred almost exclusively at 4-year colleges and universities. Increasingly, research now occurs at technical and community colleges as well. One driver of the expanded research in these settings is the increased attention paid to faculty credentials: technical colleges are encouraging faculty to seek advanced degrees, which may mean writing a thesis, and students are a convenient sample to use for thesis research. In other cases, instructors may use class time on exercises that benefit the instructor rather than the student; these projects may also be looked upon as research. Technical and community colleges also receive occasional requests from outside parties recruiting research participants. Because it is part of their traditional identity, research-oriented colleges and universities have established procedures for managing the broad spectrum of research enterprises within their domains. However, recent postings to the listserver of the National Council of Research and Planning (NCRP, an organization of research and planning administrators at two-year colleges) suggests that most technical and community colleges have limited procedures, if any, for providing oversight for research on campus. In a time of unprecedented litigation against researchers and their institutions, ensuring that the rights of research participants are being upheld can no longer be left to chance.

A common problem with research at two-year colleges is that neither the institution nor the researchers come from traditional research backgrounds. As a result, neither is familiar with standards used by traditional research institutions for the protection of human participants in research. The research that occurs at technical or community colleges is not likely to result in deaths or permanent injuries, which have resulted in a number of pending lawsuits against researchers and their universities (Blumenstyk, 2002; Milford, 2001). However, participants can experience consequences such as reduced employability, reduced social standing, or loss of confidentiality from their participation; it is only a matter of time before the ability to obtain damage settlements for these types of consequences of participation is tested in court. At least one community college has learned that students will react strongly when they perceive themselves to be mistreated as research participants; a group of students responded to being asked to help norm a test for a third party during class time by marching on the president's office

in protest (Kawahara, 2002). This unfortunate situation could have been avoided if the standard practices for reviewing research projects had been in place at this institution; without them, it could happen to any of us.

This paper will draw on two years of delving into these issues by the Ethics Advisory Team of the Research, Planning and Development subcommittee of the Wisconsin Technical College System (WTCS) President's Association. This paper will share what we have learned about Institutional Review Boards (IRBs), their relationship to the realities of two year institutions, how institutional research work relates to IRBs, how state and federal legislation further complicates already complex issues—and what to do about all of the above.

Institutional Review Boards

At research-oriented colleges and universities, the standard of practice is to have an Institutional Review Board (IRB) review and approve all research projects. The phrase “standard of practice” is an important one because of its central role in legal definitions of negligence. To be found liable for negligence, it must be proven that 1) a party has been injured, 2) the liable party held a duty towards the injured party, and 3) the liable party “breached that duty by failing to conform to the required standard of conduct” (West's Encyclopedia of American Law, 1998). Of the three, it is the third that is usually the most difficult to prove. However, one standard for proving negligence is to demonstrate that the “usual and customary conduct or practice of others under similar circumstances” (West's Encyclopedia of American Law, 1998) was not being followed. Because IRBs define the standard of practice in reviewing research, research at technical and community colleges faces possible claims of negligence when they fail to conform to those standards.

The creation and operation of formal IRBs are governed by federal statutes 45 CFR 46. However, 45 CFR 46 is limited in its authority to organizations that receive research support from any of the branches of the Department of Health and Human Services (DHHS); to receive DHHS research funding, a research project must be approved by an IRB that is registered with the DHHS. In most cases, when a research institution registers with DHHS, it includes an assurance that *any* project involving human participants that takes place at that institution will be reviewed and approved by the IRB. Because community and technical colleges have not traditionally competed for such grants, they have not been required to establish IRBs. Any community or technical college can register an IRB with DHHS, but there are reasons why they might prefer not to. The rules governing IRB composition are quite specific and require the involvement of experts from many areas and individuals not otherwise associated with the institution. The costs involved in finding and retaining the committee, plus the necessity of renewing the IRB assurances at the DHHS and maintaining the necessary paperwork, means that substantial resources are required to form and maintain an IRB. A research-oriented institution can offset these costs through their retention of indirect cost percentages from grants received; two-year colleges are not likely to have this source of revenue and would have to support the IRB from operational funds. At a time when money is tight and some colleges very existence is threatened by state budget cuts, funding for an IRB is not likely to be readily available. However, if the goal is to avoid liability, there might be a less costly alternative: an IRB that follows the procedural rules of 45 CFR 46 but is not formally registered with the DHHS. The

theory behind this proposal is that following 45 CFR 46 meets the expected standard of practice, while bypassing DHHS allows the IRB to utilize existing college resources and perhaps even be shared by multiple schools. A trial lawyer might still argue that an IRB that is unregistered and/or comprised entirely of members associated with the institution falls below the expected standard of practice met; however, this middle ground is far better than doing nothing, and by implementing time-tested review procedures the institution can hopefully avoid any unfortunate events that would land them in court in the first place.

IRBs and Institutional Research

What about Institutional Research? We have projects working all the time; have we been remiss by not getting IRB approval for our work? Not necessarily; consider the DHHS definition of research:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102 (d))

Since the primary purpose of most IR projects is to assess outcomes for a specific institution (i.e. job placement of graduates) rather than generalizable knowledge, many IRBs consider IR projects to be outside of their purview (although at least a few research departments do seek IRB approval for their projects; L. Attinasi, personal communication, September 24, 2002). However, this does not mean that Institutional Researchers can safely operate in ignorance of IRBs and their functions; our theme here is to help technical and community colleges limit their liability by instituting a formal research oversight process, and whether or not a research participant sues you is not limited by any federal definition. Furthermore, Institutional Research projects that start out with a local intent sometimes grow into projects that can be conceived of as producing generalizable knowledge: how much of the data being presented at this AIR Annual Forum was intended, at the outset, to be shared with a national audience? Thus, while it might not be necessary to have an IRB approve every graduate follow-up survey, IR projects should be conducted in line with DHHS expectations in order to reduce liability.

Probably the research ethics issue that comes up most frequently in institutional research has to do with maintaining the confidentiality of respondents. IRBs are very clear that participant identity must be protected from direct *or indirect* risk of exposure. Indirect identification occurs when some combination of specifying information makes it possible to deductively identify the source of that information. Consider the following data from our 2001-2002 Graduate Follow-up Survey:

Property Appraisal/Assessment

Associate's Degree

Graduates	3
Respondents	2
Employed	2
Related Occupation.....	1
Unrelated Occupation	1
Full-time.....	1
Part-time.....	0
Seeking Employment.....	0
Job Titles and Employers (full-time related employment)	
<i>Appraiser Relocation Specialist, City of Milwaukee, Milwaukee, WI</i>	

Normally the average salaries of graduates would be reported as well, but in this instance it was withheld because only one of the three program graduates was employed in a related profession (only employed-related salaries are reported). To report his or her salary would at minimum publicize the salary paid by the City of Milwaukee to appraisers; we have no permission from the employer to make this information public. Second, if anyone associated with the program learned that a particular graduate was now working for the city—or, a city employee learned that a co-worker had gone to WCTC—the annual income of that individual has now been exposed. Now consider some worse-case scenarios: what if that graduate was earning very low wages? Not only is loss of confidentiality a risk category in itself, this graduate could now also be exposed to social risk (peers lower their opinion of this person because he or she is working at low wages) and economic risk (potential references might lower their opinion of this person if they associate the person’s income as a measure of his or her employability). What if the student had provided feedback that was unfavorable toward the program—what social and economic repercussions might arise then? Because we cannot know what additional knowledge of our graduates our readers might possess, and because we cannot predict what consequences might come with disclosure, Institutional Researchers need to be conservative in ensuring the confidentiality of their respondents.

Legal Issues

FERPA

Not only is it a good idea to keep a close eye on unintended losses of confidentiality from a liability perspective, but also any breeches of confidence will also usually violate the Federal Educational Rights and Privacy Act (FERPA). FERPA prohibits non-consensual disclosure of personally identifiable information contained in education records without the written consent of the student or his or her legal guardian; in Wisconsin, the Supreme Court has also affirmed that this pertains to records that can only indirectly be identified (*State ex.rel. Blum v. Board of Education*, 1997). A point of clarification about FERPA: it is funding legislation, not criminal code. This means that if an institutional researcher accidentally allows confidential information to become known, he or she has not committed a felony. It could, however, lead to that institution being banned from receiving Federal financial assistance, including the majority of

financial aid to students, in essence driving your college out of business. FERPA confidentiality issues are such a major concern to institutional researchers because our customers demand specific details from our findings, unlike most “pure research.” Nobody would think to ask the annual salary of the participants in a cancer study, but this is exactly what an academic department wants to know about its graduates. To address these specific demands, many colleges and universities provide their customers with the capability of drilling-down into the specifics of their data (using OLAP cubes or similar tools). Drilling-down, however, can create data cells with only one or two cases in them, which could result in the indirect identification of participants. As an example: unless your institution is very diverse, inclusion of ethnicity with other data can be a major doorway to small cell problems. As an example, there were 292 graduates of our Certified Nursing Assistant program in 2001-2002, of whom 90% were female. When the minority gender (male) is crossed with a minority ethnicity (Hispanic), we have isolated a single graduate. Any information presented about this individual would be just as identifiable as if his name were printed on the page.

FERPA does not protect what is considered directory information—things like student addresses and phone numbers. Institutions must be alert, however, that a request for directory information might contain an indirect request for protected information. An all-female college recently requested the names of recent graduates of our 2-year accounting program in order to recruit for their four-year program. Date of graduation and college major are directory information, *but gender is not*; we could provide them with a list of *all* graduates of the program, but if we selected out only those graduates that were female, we have indirectly identified the gender of the students whose names we provide, in violation of *FERPA*.

Although FERPA is not new, in the wake of September 11, 2001, a significant exception to FERPA was introduced into law (*Uniting and strengthening America act by providing appropriate tools required to intercept and obstruct terrorism [USA Patriot Act] act of 2001*) that is generally known as the Patriot Act. College officials must now provide the Attorney General with information about students being investigated in connection with terrorist activities in response to an *ex parte* (without the knowledge of the third party) court order. Furthermore, the college does not need to note that a release of information has occurred in the student’s official record, as they would be required to do in other instances. Patriot Act requests are more likely to go to registration or other records officers, but IR professionals should be aware of it nonetheless.

The Freedom of Information Act

The Patriot Act is one path whereby information that should be protected from the perspective of participant protection and FERPA might nevertheless need to be released on some other legal basis. Another legal means whereby a third party might try to obtain confidential information from your office is through the Freedom of Information Act (FOIA; 5 U.S.C. § 552, As Amended by Public Law No. 104-231, 1996). The original FOIA was broadened in scope by the Shelby Amendment (Public Law No. 105-277, 1998) to include research data. Originally passed in response to Harvard University’s refusal to disclose the raw data behind a study that provided key justification for a new EPA pollution regulation (Azar, 1999), the Shelby Amendment was written so broadly that in theory any research data could have been requestable

and, as such, would have all but halted research as we know it. Fortunately, the application of the FOIA to research data is currently limited by the Office of Management and Budget Circular A-110 (1999), whereby only research that is funded by federal sources *and* affects government actions that have “force and effect of law” (OMB Circular A-110, 1999) are subject to FOIA requests. This means that, at present, Institutional Research data does not fall under the jurisdiction of the Freedom of Information Act.

“Open Records” Laws

Although Institutional Research may be beyond the reach of the FOIA, individual states also have laws that define what official records must be made publicly available. To the extent that these laws proclaim that all government records shall be available to the public—Wisconsin’s says “except as otherwise provided by law, any requester has a right to inspect any record” (Wis. Stat. 19.35)—these laws are referred to as “open records” laws. In an open records state, any information collected by institutional researchers at a public institution is potentially subject to disclosure. The legal attitude towards the importance of open records was recently proven by a Wisconsin Supreme Court decision whereby the University of Wisconsin was required to release unprotected information even though it required masking other, protected information from thousands of individual records in order to comply with the information request (*Osborn v. Board of Regents of the University of Wisconsin*, 2002); if nothing else, it says that it is a good idea to keep personally identifiable information (names, social security numbers, etc.) off of survey forms!

Reports that are published on a public institution and funded by public money obviously need to be public reports—but what about internal documents? Worse yet—could the raw surveys themselves be obtained through open records? Each state’s interpretation of what might be obtainable through open records legislation is found in its judicial history, and even then the answers are probably unclear. For instance, there is a legal precedent in Wisconsin for a promise of confidentiality to be a sufficient reason for denying an open records request (*Mayfair Chrysler-Plymouth v. Baldarotta*, 1991). However, that decision had to do with confidentiality promised to a Department of Revenue informant, and might not be applicable to confidentiality promised to survey respondents. Furthermore, the Attorney General clarified the scope of this decision by adding that a promise of confidentiality cannot be maintained if the document is obtained under a specific statutory right (60 Atty Gen. 284); since many of our projects fulfill requirements of our state system, this interpretation might be used to force us to release records where we had promised confidentiality. Clearly, institutional researchers face potential legal conflicts to the best interest of their research participants; all of these concerns should be considered when creating informed consent materials.

BROC—Big Researcher on Campus

There is one final, unrelated and purely practical reason why institutional researchers at two-year colleges ought to know about IRBs and how they view research—since the majority of the faculty are not trained as researchers, IR may be the primary source of research expertise at your institution. As such, you may be consulted about projects that have nothing to do with your role as the Institutional Researcher because you may be the only person(s) on campus with the required expertise. In the absence of an entity designated with responsibility for research

oversight, any research ethics questions—or worse yet, after-the-fact problems—will probably be directed to the IR office. Trying to clean up a mess already in progress could potentially increase your own personal exposure to litigation.

IRBs and Community and Technical Colleges

For all of the preceding reasons, it is recommended that even two-year colleges institute some form of IRB to review research that occurs on campus. What exactly is involved with forming an IRB? This is not a venue for discussing all of the intricacies of 45 CFR 46, but for those unfamiliar with how IRBs operate, this thumbnail sketch describes what is all involved.

How IRBs Work

IRBs have two major functions: to conduct a cost-benefit analysis to evaluate the potential risks to participants compared with the benefits obtainable from the research, and to ensure that participants are able to freely choose whether or not to participate in the research. With regard to risk, there are many kinds of risks that a research participant may be exposed to, such as:

- Physical risk: physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research.
- Psychological risk: alteration of behavior or the production of negative affective states such as anxiety, depression, guilt, shock, or loss of self-esteem.
- Social risk: alterations in relationships with others that are to the disadvantage of the participant, including embarrassment, loss of respect of others, or labeling a participant in a way that will have negative consequences.
- Economic risk: includes payments for procedures not otherwise required, loss of wages or other income, and any other financial costs, such as damage to a participant's employability.
- Legal risk: the participant or others will be liable for a violation of the law, either by revealing past actions or requiring future actions that may be criminally or civilly liable.
- Loss of confidentiality: participants have the right to be protected against invasions of their privacy and to preservation of their personal dignity.

Regardless of the type of risk, however, is level of risk, and here the key concept is *minimal risk*. Minimal risk is defined as risk whose magnitude and probability are equivalent to that which would be experienced in everyday life, such as those an individual might experience had they chosen to not take part in the research. When a project involves more than minimal risk, researchers must be able to justify this risk by the obtainable benefits.

Just as minimal risk is the key concept regarding risk, *informed consent* is the key concept regarding free choice. Participants have the right to be informed in advance of the risks and benefits they might expect from participating, and from that make an informed decision whether to participate. Researchers bear responsibility for demonstrating that these conditions are met, which is why consent documentation is so important; in practice, inadequate consent documentation is probably the most common reason for delayed approvals. Most research projects require that a signed consent form must be retained documenting the expected risks and benefits, any costs associated with participation, and alternatives to participation. The consent

form also must inform participants that they have the right to withdraw their consent at any time without penalty (researchers unfamiliar with IRBs usually don't know that participants must be given this option) and explains whom to contact in case of later problems. Note that a consent form does not and legally can not indemnify the researcher or his or her institution from liability for consequences suffered, whether anticipated or not. Researchers also bear responsibility for rectifying damages stemming from participation.

IRBs have three procedures for reviewing the cost-benefit balance and the adequacy of informed consent in research protocols. The criteria for qualifying for one type of review over another are set by 45 CFR 46, helping ensure consistency of review across individual IRBs. An *exemption review* determines whether a project requires review at all based on the level of risk and of human participation; anonymous surveys and use of archival data, for example, can be exempt under certain conditions. If a project does require IRB review, it can be reviewed using either an *expedited* or a *full review* procedure. Expedited review is an approval (from the IRB chair alone) of a project that involves no more than minimal risk and meets other specific criteria related to data type and collection method; otherwise, the protocol is reviewed by the full committee. To illustrate the levels of risk, review, and consent, imagine a simple student opinion survey. If the survey were conducted anonymously, it would qualify for IRB exemption as long as there was no more than minimal risk; choosing to return the survey would generally be considered sufficient proof of consent. Most of the time, institutional researchers don't do anonymous surveys, however: they code surveys so that they can determine who has responded and can follow-up with those that have not. This same, minimal-risk survey would now require (expedited) review and a formal consent procedure, although it might qualify for a "waiver of documentation of consent." A waiver of documentation of consent requires conformity to all of the disclosure considerations of a consent form, but does not require that a separate, signed consent form is retained as proof; instead, the cover letter serves as the consent form, and returning the survey serves as proof of consent. If, however, there were more than minimal risk—asking students about alcohol or drug use, for instance, which could expose them to risks should the answers be traced back to their source—both full review and formal consent documentation would be required.

Recommendations

After reviewing the liability and legal issues as well as the procedures used by IRBs, the Ethics Advisory Team recommended to its member technical colleges that they should act now to institute some form of IRB that followed the guidelines of 45 CFR 46, but each college was left on its own to decide how research review procedures would be implemented. Five possible scenarios were suggested—the idea of a single, system-wide IRB was rejected as not feasible—with the benefits and drawback of each spelled out (see Table 1). Forming a formal, registered IRB or contracting with an independent registered IRB on a project-by-project bases were possibilities, but it was anticipated that these would be cost-prohibitive for most. Having a formal IRB on-site also introduces a lot of administrative overhead, while contracting for third-party services carries an inherent risk of changing vendors and, associated with it, changing procedures (the vendor would have to be picked by our open bidding process). Having a single

Table 1: Benefits and Drawbacks of Means of Implementing IRBs at a Community or Technical College

	Formal (Registered) IRB	Local IRB	Shared IRB	Third-party (Registered) IRB	Compliance officer
Liability protection	Maximum; this is the standard	Can have good procedures, but not being registered increases liability risk	Same as local IRB	More, but will require indemnification of IRB should something go awry	Minimal if any; below the expected standard of practice
Cost	Time of staff; travel and possible expenses/stipends for community members	Time, not money	Time, plus some travel	Potentially Prohibitive	Time, not money
Potential for conflict of interest/pressure	Least/Distributed	Distributed, but all members part of a single organization	Distributed; may lead to inequity of effort between colleges	Limited to pressure to retain contract	Maximum
Workload	Shared within college	Shared within college	Shared between colleges, hence more work than single-college IRB	Minimal; liaison with IRB	Potentially overwhelming for one person
Difficulty of formation	Very: must apply with DHHS and file semi-annual assurances	Limited to identification of appropriate members	Additional requirement of coordination between colleges (and missions/agendas)	Formal bid process	Little
Committee membership	Fixed rules make this difficult to fill (add list of requirements)	Existing staff	Existing staff	None	One person
Committee size (external/internal)	Fixed by regulations (state minimum)	Can be smaller because college sets own standards (internal)	Might be smaller, depending on desire for representation by each college (all internal)	Fixed by regulations (all external)	One (internal)
Continuity in case of member departure	Existing committee members can mentor new ones and maintain operations; training external members would be a more intensive process	Existing committee members can mentor new ones and maintain operations	Existing committee members can mentor new ones and maintain operations	External concern; contract bidding may lead to changes in vendor/procedures from year to year	Operations would be suspended until new individual learns procedures
Response Time	Fixed schedule	Fixed schedule; may be easier to schedule more frequently as all staff are on-site	Fixed schedule, but may have to meet less frequently on account of travel	Outside of college control	Variable dependent on individual's workload
Ease of gaining project approvals	More difficult: non-scientifically trained members may require more explanation	Routine	Routine, but may involve additional discussions to understand local practices	Varies	Easiest
Institutional Control	Full	Full	Half	None; external group is autonomous	Full
Sufficient for DHHS Research Funding?	Yes	No	No	Yes	No

research compliance officer approve all research was also not recommended because it was perceived to fall short of the standard of practice and therefore did not satisfy the primary objective of reducing liability. This left two solutions that were suggested as being most likely to be feasible for implementation: forming a local, non-registered IRB, or forming a local, non-registered IRB that is shared with one or more neighboring institutions. Shared IRBs reduce the staffing load of any single college, but introduce travel costs and possible delays, plus additional coordination issues.

At this time, the member colleges are at different points in introducing procedures at their schools. Two technical colleges have IRBs already operating, and a third has proposed policy changes that will lead to one's formation. It is our recommendation that any community and technical colleges that do not have access to an IRB should seriously consider the risk potential and begin the process of formalizing procedures to protect research participants at their schools.

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Author Note

Viktor Brenner, Department of Research and Evaluation Services, Waukesha County Technical College.

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Correspondence concerning this article should be addressed to Viktor Brenner, Department of Research and Evaluation Services, Waukesha County Technical College, 800 Main Street, Pewaukee, WI 53072. Email: vbrenner@wctc.edu