January 2012

Have Institutional Review Board Regulations Affected Research Approval Patterns?

John W. Hill
University of Nebraska at Omaha, jhill@unomaha.edu

Advances in Medical Psychotherapy and Psychodiagnosis, Vol. 13, 2012-2013

Have Institutional Review Board Regulations Affected Research Approval Patterns?

John W. Hill

University of Nebraska at Omaha

Kevin J. Epperson and Gail D. Kotulak

University of Nebraska Medical Center

Abstract

Medical and comprehensive university Institutional Review Board for the Protection of Human Subjects research protocol approval rates and days to approval, before and after the implementation of governmentally imposed accountability, privacy, and protection regulations, were evaluated. We hypothesize that Institutional Review Board regulatory over-interpretation would result in decreased research protocol approval rates and increased days to approval particularly on the medical campus where researchers rely most heavily on protected Private Health Information. A chi-square was used to determine pre-regulation compared to post-regulation research protocol approval rates while a dependent *t* test was used to evaluate pre-regulation compared to post-regulation days to approval for each campus. In addition a chi-square was used to measure differences between post-regulation medical campus and post-regulation comprehensive campus exempt, expedited, and full board protocol submission category percentages while an independent *t* test was used to compare intercampus post-regulation days to approval to clarify what researchers may expect in this ongoing post-regulation period when they submit their research to the IRB for review. We conclude that while the regulatory burden of researchers has increased this has not resulted in significantly fewer research protocols receiving approval and a timely review on either campus. Moreover, investigators increased awareness of accountability, privacy, and protection regulation may provide additional safeguards for research participants.

Background

Recorded clinical data and information have long been used to advance understanding of diseases and evaluate the effectiveness of innovative medical therapies. Social/Behavioral research, also relying in part on clinical and individual client case study information, has resulted in untold benefit to individuals and society. However, there is concern that neither clinical investigators, frustrated by a seemingly bureaucratic and inefficient review process, nor Institutional Review Board (IRB) for the Protection of Human Subjects committee and staff members, attempting to clarify complex and often contradictory regulations, are satisfied with the protections for participation in human research (Wood, Grady, & Emanuel, 2004). Governmentally imposed accountability (Health Insurance Portability and Accountability Act, [HIPAA]; 1996), privacy (Family Education Rights and Privacy Act, [FERPA]; 1997), and protection (Protection of Pupil Rights Amendment, [PPRA]; 2001) regulations have increased

the complexity of existing rules and the potential for confusion. The primary purpose of HIPAA is to ensure the adequate handling of individually identifiable Protected Health Information (PHI) when transmitted in electronic form between covered entities, defined by HIPAA as a health care provider, a health plan, or health care clearinghouse. The Family Education Rights and Privacy Act is a federal law that applies to educational agencies and institutions that receive federal funds under any program administered by the Secretary of Education. Generally, FERPA prohibits the funding of an educational agency or institution that has a policy or practice of disclosing a student's educational record without the consent of the parent or eligible student. The Protection of Pupil Rights Amendment, covers student privacy, parental access to information, and administration of certain physical examinations to minors. The Protection of Pupil Rights Amendment also applies to surveys funded in whole or part by any program administered by the U.S. Department of Education.

Protected Health Information is defined in the Code of Federal Regulations (CFR) as individually identifiable health information about an individual, including demographic information (45 CFR 160.103, 2003; 45 CFR 164.501, 2005) that relates to the individual's past, present, or future health or condition, the care provided, or the payment history of the individual (45 CFR 160.103, 2003) that is transmitted or maintained in any form or medium. Given the scope of these regulations, researchers now are generally advised to consult IRB staff about conducting a new analysis on old data sets to insure compliance with HIPAA when using PHI, particularly if the data were collected under an IRB-approved protocol that has lapsed--a layer of complexity unnecessary before accountability regulation (Horner & Wheeler, 2005). Also of concern is whether, in assessing the impact of research on the privacy rights and welfare of individual research participants, IRB committee members will "invite irresolute debate about privacy rights and the appropriate measures and standards for weighing them against the benefits of research" (Kulynych & Korn, 2002, p. 202).

The Common Rule

While the Privacy Rule was established to govern the use of HIPAA, PHI for treatment, payment, and health care operations, the Common Rule governs the use of PHI for research (45 CFR 46, 2005). Universities fall under the Common Rule because universities receive Department of Health and Human Services funds and are therefore covered by multiple-project or federal-wide assurances. The Common Rule requires informed consent for participation in research, addressing not only risks and benefits, but also respecting and safeguarding privacy and confidentiality of an individual with respect to identifiable information. For the purposes of the Common Rule and the IRB review process, the federal regulations define research as "systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge" (45 CFR 164.501, 2005). Regulations define a human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information" (45 CFR 46.102(f), 2005). Data collected may include individual PHI. Institutional Review Board members and staff are charged with the responsibility to (a) protect the rights and welfare of research participants, (b) ensure compliance with all federal, state, and local laws and regulations regarding the conduct of research in humans, and (c) facilitate the research process (Epperson, 2006). The IRB is a volunteer committee of at least five members of diverse race, gender, and cultural backgrounds who are both knowledgeable and experienced

in working with all forms of prospective research subjects, including children, prisoners, pregnant women, handicapped, or mentally disabled persons (45 CFR 46. 107(a), 2005). Inclusion of participants in research and unauthorized solicitation of research participants without informed consent is subject to institutional and/or individual sanctions by the Department of Health and Human Service's (DHHS) Office for Human Research Protections (OHRP). The Department of Health and Human Service's Office of Civil Rights, enforces the Privacy Rule while the informed consent regulation of the Common Rule is enforced by DHHS's OHRP. The process of obtaining informed consent for research is governed by the IRB.

Since April 14, 2003, all researchers have been required to include PHI language in participant informed consent documentation for research involving the collection of PHI (45 CFR 164.508, 2005). Including the HIPAA authorization within the body of the research consent document, as opposed to utilizing a separate, stand-alone document, was an alternative that many universities elected. Also, from the April 14, 2003 date forward it is required that protocols and consent documents submitted for IRB review, without PHI language, be returned to investigators with directive comments from IRB staff about inclusion of PHI language before review. Standard PHI language is now routinely included in consent documents replacing the need for separate PHI documentation. The following sample adult consent document language from the Biomedical Consent Form template (2004) serves to satisfy PHI and research language requirements:

> "You have rights regarding the privacy of your medical information collected before and during this research. This medical information, called 'protected health information' (PHI), includes demographic information (like your address and birth date), the results of physical exams, blood tests, x-rays, and other diagnostic and medical procedures, as well as your medical history. By signing this consent form, you are allowing the research team to have access to your PHI. Your PHI will be used only for the purpose(s) described in the section 'What is the reason for doing this research study?' Your PHI will be shared, as necessary, with the Institutional Review Board (IRB) and with any person or agency required by law." (p. 6)

Implementation and Cost

Implementation of accountability regulations has also been costly. For example, at Johns Hopkins University, 26,000 employees had to take HIPAA compliance training and pass examinations with an overall estimated cost of nearly $2 million in the first year (Friedman, 2006). Public and private universities and institutions routinely require researchers to complete on-line training courses that focus on (a) justice, (b) respect, and (c) beneficence as the guiding principles and analytical framework for resolving ethical problems associated with the protection of human subjects of biomedical and behavioral research (The Belmont Report, 1979). One such course, with accompanying examinations, in the protection of human research subjects is the Collaborative IRB Training Initiative (CITI; https://www.citiprogram.org/default.asp). The Collaborative IRB Training Initiative is designed as a minimum level of ethics training for individuals involved in human subjects research. CITI includes sections on HIPAA and PHI requirements for researchers. CITI is required of all research investigators and participating personnel (faculty and students) and

offers biomedical and social/behavioral science modules, with certification valid for 3 years. Typically, researchers must hold certification in order to conduct research.

Even with these guiding principles there is a growing concern that researchers, out of frustration with regulatory mandates, training, and perceived lengthy review times, would break rules, such as collecting data before receiving IRB approval. According to Martinson, Anderson, and de Vries (2005) researchers who felt that governing bodies had unfairly treated them may be more likely to engage in research misconduct. In fictional situations where researchers were refused permission to conduct a study by an IRB and were responded to in a curt manner, rather than receiving an explanation, subjects empathized with the rejected researcher and were less likely to assign a significant punishment if the researcher went ahead and ran the study without IRB approval.

Research Questions

Despite the level of concern expressed about regulation having a chilling effect (Ness, 2005) on research practices, no studies to date have been completed on the impact of these mandates on IRB protocol approval rates and time to approval. Our study addressed the following research questions: Has governmentally imposed accountability, privacy, and protection regulation been over-interpreted during the IRB review process, resulting in the unintended consequence of: (a) reduced research protocol approval rates and (b) increased days to approval. We also wanted to determine if there were differences between medical and comprehensive campus post-regulation exempt, expedited, and full board protocol submission category percentages and days to approval?

Procedures

In our critical case study we hypothesized that if regulations were interfering with research practices, as represented by (a) decreased post-regulation protocol approval rates and (b) increased post-regulation protocol days to approval, we would be most likely to find this interference occurring on the medical campus where researchers rely heavily on PHI. We examined comprehensive university protocol approval rates and days to approval hypothesizing that we would be less likely to find this interference occurring on the comprehensive campus where researchers rarely rely on PHI. Eighteen-month pre-regulation (October 1, 2001 to April 13, 2003) and 18-month post-regulation (April 14, 2003 to September 30, 2004) served as our study independent variable. We chose the post-regulation date (April 14, 2003) because that was the date institutions were to have all HIPAA safeguards and procedures in place for accountability purposes ("HIPAA takes," 2003). Eighteen months pre-regulation to 18-months post-regulation was selected as the study time period to insure an adequate sample size. We included those medical and comprehensive university departments in this study that had a pre-regulation record of IRB research protocol approvals.

Data Analysis

Inferential chi-square (X^2) data analyses were conducted for pre-regulation compared to post-regulation medical university exempt, expedited, and full board protocol approval rates and pre-regulation compared to post-regulation comprehensive university exempt, expedited, and full board protocol approval rates. Dependent *t* tests were utilized to analyze pre-regulation compared to post-regulation medical university protocol days to approval and

pre-regulation compared to post-regulation comprehensive university protocol days to approval. We also examined post-regulation medical campus protocol submission category percentages and days to approval compared to post-regulation comprehensive campus protocol submission category percentages using chi-square. An independent *t* test was used to compare post-regulation medical campus to post-regulation comprehensive campus protocol days to approval.

Our study had several strong features as constants including: (a) the study medical university and comprehensive university are two campuses of the same university system and are located in the same large metropolitan area, (b) both universities are regulated by the same unified IRB and all protocols were reviewed by the same IRB, (c) the IRB met twice each month, on the first and third Thursdays, throughout the pre-regulation and post-regulation periods of this study, (d) the pre- and post-regulation period was one of IRB regulatory staff (n = 5) and faculty and community IRB membership (n = 20) stability, and (e) all investigators from both the medical and the comprehensive campuses and all IRB staff and community and faculty membership had completed CITI.

Our study did not differentiate between pre-regulation or post-regulation research projects that were supported by industry (for example, drug companies) or government (for example, National Institutes of Health) grants. We also did not make any distinction between research projects initiated by faculty and/or graduate students in M.S., Ph.D., Ed.D., and M.D. degree programs because the procedures for research protocol submission and review are identical for students and faculty.

Sources of Data

Medical university research protocols from 36 departments (see [1] Footnote) included (a) investigational drugs and devices, (b) Food and Drug Administration approved drugs and devices, (c) cancer studies, (d) cellular and genetics research studies, (e) patient information studies, (f) chart reviews, (g) health screenings, and (h) exercise science studies. Methodologies included cohort studies, case-controlled trials, and randomized controlled trials. Drug clinical trials are classified into four phases and require many years to complete. Some medical research also employed survey, interview, focus group, program evaluation, cross-sectional, and longitudinal methodologies. Participants were adults and children. Comprehensive university research protocols from 14 departments (see [2] Footnote) included individual and group characteristics of behavioral research on (a) perceptions, (b) cognition, (c) motivation, (d) achievement, (e) behavior, (f) identity, (g) language, (h) communication, (i) cultural beliefs or practices, and (j) social behavior. Research employed experimental, quasi-experimental, survey, interview, focus group, and program evaluation methodologies. Participants were adults and children. Researchers from both campuses submitted protocols under exempt, expedited, or full board review category regulations using on-line forms and the following category descriptors:

(1) Exempt review research is conducted in established or commonly accepted educational settings, involving normal educational practices. Educational research protocols are exempt providing all of the following conditions are met: (a) all of the research is conducted in a commonly accepted educational setting, (b) the research involves normal educational practices, (c) the study procedures do not represent a significant deviation in time or effort requirements from existing educational practices, (d) the study procedures do not

involve sensitive topics (e.g., sex education), (e) provisions are made to ensure a non-coercive environment for non-subjects, and (f) the school or other institution grants written approval for the research to be conducted. Additionally, exempt research may involve the use of educational tests, survey or interview procedures, or observation of public behavior unless the information is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and any disclosure of the human subjects' 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. Also, exempt research may involve the collection or study of existing data, documents, records, pathological 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. Note, however, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or children.

(2) Expedited review research activities (a) present no more than minimal risk to human subjects and (b) involve only procedures listed in one or more of the following categories: clinical studies of drugs and medical devices for which an investigational new drug (IND) application is not required, collection of blood samples by finger/heel/ear stick or venipuncture, collection of biological specimens for research purposes by noninvasive means, (e.g., hair and nail clippings); data from voice, video, digital, or image recordings made for research purposes, individual or group characteristics or behavior; or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or QA methodologies.

(3) Full Board research requires review by the full committee due to the complexity of the research proposal, the risk classification (greater than minimal), use of a drug, device or biological material, or the population under study. Examples include: research involving prisoners, studies involving maximal exercise testing, and use of unconventional psychological testing instruments (Epperson, 2006).

Results

The pre-regulation compared to post-regulation IRB medical campus data summary is found in Table 1. We hypothesized that if regulations were interfering with research practices, as represented by decreased post-regulation protocol approval rates and increased post-regulation protocol days to approval, we would most likely find this interference occurring on the medical campus where researchers rely heavily on PHI. Study results indicate no significant medical university pre-regulation compared to post-regulation protocol approval rate difference where $X^2(2, N = 948) = 3.92$, $p = .20$. We also found no significant pre-regulation days to approval ($M = 46.00$, $SD = 29.64$) compared to post-regulation days to approval ($M = 42.44$, $SD = 36.48$) difference for dependent t test results, where $t(35) = -0.61$, $p = .27$ (one-tailed), $d = .10$. Overall, 16 fewer post-regulation medical university protocols were approved ($n = 466$) for one less researcher ($n = 249$) requiring 3.56 fewer calendar days (42.44) to approval. Our hypothesis for medical campus pre-regulation compared to post-regulation exempt, expedited, and full board category protocol approval rate and days to approval difference was not supported by the data.

The pre-regulation compared to post-regulation IRB comprehensive campus data summary is found in Table 2. We examined comprehensive campus protocol approval rates and days to approval hypothesizing that we would not find interference occurring on the comprehensive campus where researchers seldom rely on PHI. Study results indicate no significant comprehensive university pre-regulation compared to post-regulation protocol approval rate difference where $X^2(2, N = 242) = 2.78, p = .30$. We also found no significant pre-regulation days to approval ($M = 22.51$, $SD = 9.68$) compared to post-regulation days to approval ($M = 27.79$, $SD = 15.28$) difference, for dependent t test results where $t(13) = 1.48$, $p = .08$ (one-tailed), $d = .42$. Overall, 22 fewer post-regulation comprehensive university protocols were approved ($n = 110$) for nine fewer researchers ($n = 100$) requiring an additional 5.28 calendar days (27.79) to approval. Our hypothesis for comprehensive campus pre-regulation compared to post-regulation exempt, expedited, and full board category protocol approval rate and days to approval consistency was supported by the data.

We also examined post-regulation medical campus protocol submission category percentages and days to approval compared to post-regulation comprehensive campus protocol submission category percentages and days to approval to clarify what researchers may expect in this ongoing post-regulation period when they submit their research to the IRB for review. The data summary is found in Table 3. Results indicate a significant difference between post-regulation medical campus compared to post-regulation comprehensive campus protocol submission category percentages where $X^2(2, N = 200) = 51.10, p < .01$. In our comparison 51% of the medical campus research protocol submissions required full board reviews while only 10% of the comprehensive campus research protocol submissions required full board reviews. On the other hand 82% percent of comprehensive campus research protocol submissions compared to 33% of the medical campus research protocol submissions were eligible for exempt review status. Nearer equipoise percentages were noted for research protocols requiring expedited review on the medical (16%) and comprehensive (8%) campuses. We also found a significant medical campus post-regulation days to approval ($M = 42.44$, $SD = 36.48$) compared to comprehensive campus post-regulation days to approval ($M = 27.79$, $SD = 15.28$) difference, for independent t test results where $t(48) = 2.00$, $p < .05$ (one-tailed), $d = .56$. Overall, medical campus research protocol reviews required an additional 14.65 calendar days for approval compared to comprehensive campus submissions. In real world terms 14.65 calendar days represents one additional bi-monthly IRB meeting cycle. Given the complexity of prospective medical studies requiring full board review we interpret this as a difference without distinction rather than a difference related to IRB regulatory guidelines over-interpretation.

Conclusion

Accountability, privacy, and protection regulation has increased the regulatory burden of researchers. However, the protocol approval rate and time to protocol approval findings of this study suggest that regulation requirements placed on researchers are unlikely to prevent research projects from being initiated and receiving timely IRB review and approval. We conclude that medical campus reviews requiring significantly more days to approval than comprehensive campus reviews is reflective of the differing nature of medical protocol submissions requiring full board review compared to the comprehensive campus where expedited and exempt reviews prevail. Moreover, we believe that investigators' increased

awareness of accountability, privacy, and protection regulation may provide additional safeguards for research participants.

Discussion

We believe our findings should prove reassuring to researchers. With hope additional human subjects compliance mandates will not inadvertently serve to curtail the *inspiration and perspiration* required for initiating, sustaining, and bringing to final fruition, scientific and research endeavors. Furthermore, while IRB review and oversight must be sufficient to meet the ethical goal of protecting human subject participants, institutional budgets and resources must adequately reflect this mandate (Sugarman, et al., 2005). These costs now must include implementing the HIPAA mandate, which has been costly to universities. Institutions must be mindful of balancing the hiring of IRB regulatory and compliance personnel with IRB support staff that are accessible to researchers. IRB staff members play a key role in providing researchers with current information, updated on-line forms, and an increased understanding of changing rules--such as the informed consent process, now considered an educational endeavor (Flory & Emanuel, 2004). Meeting certain requirements of HIPAA, IRB staff could play a key role in facilitating longitudinal, archival, and across agency subject tracking by working with researchers to request authorizations and waivers for protected health information, de-identifying data, and creating limited data sets for research (HIPAA takes center stage, 2003). Researchers may seek waivers of informed consent authorized by the IRB for de-identified or safe harbor data sets. De-identified health information is no longer PHI and therefore the requirements of HIPAA do not apply. Researchers may also use Limited Data Sets (LDS) where direct identifiers are removed. Use of LDS does not require individual consent for use but does require IRB review and approval.

We recommend that departments support and encourage investigators required to modify their tabled and returned protocols following IRB review. Although it takes additional time to respond to IRB recommendations for protocol and/or consent document modifications, IRB approval may ultimately facilitate refereed review and publication of completed studies as journal editors increasingly require "Documented review and approval from a formally constituted review board (Institutional Review Board or Ethics committee)...for all studies involving people, medical records, and human tissues" (World Association of Medical Editors, 2006, p. 2). Finally, we believe that accountability, privacy, and protection regulations and the IRB review process are fully compatible with the hoped for outcomes of all research endeavors--individual and/or societal benefit.

References

1. Biomedical Consent Form Template. (October 25, 2004). The University of Nebraska Medical Center, Institutional Review Board for the Protection of Human Subjects: Omaha, NE.
2. Common Rule, 45 CFR 46. (2005).
3. Epperson, K. J. (2006). IRB 101. *The University of Nebraska Medical Center/University of Nebraska at Omaha Institutional Review Board Orientation and Overview.* The University of Nebraska Medical Center, Institutional Review Board for the Protection of Human Subjects: Omaha, NE.
4. Family Education Rights and Privacy Act. (1997). 34 CFR 99.

5. Flory, J., & Emanuel, E. (2004). Interventions to improve research participants' understanding in informed consent for research. *Journal of the American Medical Association, 292,* 1593-1601.
6. Friedman, D. S. (2006). HIPAA and Research: How have the first two years gone? *American Journal of Ophthalmology, 141,* 543-546.
7. Health Insurance Portability and Accountability Act. (1996). 67 FR 53181.
8. Health Insurance Portability and Accountability Act. (2003). 45 CFR 160.
9. Health Insurance Portability and Accountability Act. (2005). 45 CFR 164.
10. HIPAA takes center stage as implementation date nears for IRBs, clinical research sites. (2003).
11. *Clinical Trials Advisor, 8,* 1-5.
12. Horner, J., & Wheeler, M. (2005). HIPAA: Impact on research. *The ASHA Leader, 10*, 8-9 & 26-27.
13. Kulynych, J., & Korn, D. (2002). The effect of the new federal medical-privacy rule on research. *The New England Journal of Medicine, 346,* 201-204.
14. Martinson, B. C., Anderson, M. S., & de Vries, R. (2005). Scientists behaving badly. *Nature, 435*, 737-738.
15. Ness, R. B. (2005). A year is a terrible thing to waste: Early experience with HIPAA. *Annals of Epidemiology, 15,* 85-86.
16. Protection of Pupil Rights Amendment. (2001). 34 CFR 98.
17. Sugarman, J., Getz, K., Speckman, J. L., Byrne, M. M., Gerson, J., & Ezekiel, E. J. (2005). The cost of Institutional Review Boards in academic medical centers. *The New England Journal of Medicine, 352,* 1825-1827.
18. The Belmont Report. (1979). Ethical principles and guidelines for the protection of human subjects of research. *The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.* DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014. (http://ohsr.od.nih.gov/guidelines/belmont.html).
19. Wood, A., Grady, C., & Emanuel, E. J. (2004). Regional ethics organizations for protection of human research participants. *Nature Medicine, 10,* 1283-1288.
20. World Association of Medical Editors. (2006). Recommendations on Publication Ethics Policies for Medical Journals. (http://www.wame.org/pubethicrecom.html).

About the Authors

John W. Hill, Ph.D., serves as Professor, Department of Educational Administration and Supervision at the University of Nebraska at Omaha. He has served on the University of Nebraska Medical Center, University of Nebraska at Omaha, combined Institutional Review Board, since 1991. Kevin J. Epperson and Gail D. Kotulak, University of Nebraska Medical Center, serve as Institutional Review Board administrators. Address: John W. Hill, Ph.D., University of Nebraska at Omaha, Department of Educational Administration and Supervision, Roskens Hall 312, 6005 University Drive North, Omaha, NE 68182-0162; e-mail: jhill@mail.unomaha.edu

Authors' Note

This research project was originally presented by the first author at the July 15-16, 2006, 11th Annual American Board of Medical Psychotherapists and Psychodiagnosticians/ American Board of Disability Analysts, International Conference: Las Vegas, NV.

Footnotes

[1]Medical university departments (n = 36): Adult Hematology/Oncology, Biochemistry/Molecular Biology, Cardiology, College of Nursing, Dentistry, Diabetes/Endocrinology, Emergency Room, Eppley Cancer Research, Family Medicine, Gastroenterology, General Medicine, Geriatrics, Infectious Diseases, Internal Medicine-Education, Library of Medicine, Medical Technology, Monroe-Meyer Institute, Nebraska Heart Institute, Nephrology, Neurology, Obstetrics/Gynecology, Ophthalmology, Orthopedics, Otolaryngology, Pastoral Care, Pathology/Microbiology, Pediatrics, Pharmacy, Physical Therapy, Preventive and Societal Medicine, Psychiatry, Pulmonary Medicine, Radiation Oncology, Rheumatology, Surgery, and Transplant Surgery.

[2]Comprehensive university departments (n = 14): Arts and Sciences, Communications, Computer Science, Counseling, Criminal Justice, Education, English, Gerontology, Health/Physical Education, Information Systems, Marketing, Psychology, Public Administration, and Sociology/Anthropology.

Table 1

Pre-Regulation Compared to Post-Regulation IRB Medical Campus Data Summary

Sources	18-Months Pre-Regulation	18-Months Post-Regulation	Change	X^2	t
Departments	36	36	0		
Researchers [1]	250	249	-1		
Protocol Approval					
1. Exempt	139	153	+14		
2. Expedited	66	75	+9		
3. Full Board	277	238	-39		
4. Total	482	466	-16	3.92 *ns*	
Days to Approval					
Mean	46.00	42.44	-3.56		-0.61 *ns*
(*SD*)	(29.64)	(36.48)			

[1] Note: Faculty and graduate student protocols

Table 2

Pre-Regulation Compared to Post-Regulation IRB Comprehensive Campus Data Summary

Sources	18-Months Pre-Regulation	18-Months Post-Regulation	Change	X^2	*t*
Departments	14	14	0		
Researchers [1]	109	100	-9		
Protocol Approval					
1. Exempt	99	90	-9		
2. Expedited	20	9	-11		
3. Full Board	13	11	-2		
4. Total	132	110	-22	2.78 *ns*	
Days to Approval					
Mean	22.51	27.79	+5.28		1.48 *ns*
(*SD*)	(9.68)	(15.28)			

[1] Note: Faculty and graduate student protocols

Table 3

Post-Regulation Compared to Post-Regulation IRB Medical Campus Compared to Comprehensive Campus Data Summary

	Post-Regulation				
Sources	Medical	Comprehensive	Difference	X^2	*t*
Protocol Submission Category Percentages [1]					
1. Exempt	33	82			
2. Expedited	16	8			
3. Full Board	51	10			
4. Total	100	100		51.10 **	
Days to Approval					
Mean	42.44	27.79	14.65		2.00*
(*SD*)	(36.48)	(15.28)			

[1] Note: See Table 1 and Table 2 for corresponding IRB protocol approval category frequencies. *$p < .05$. **$p < .01$.

Advances in Medical Psychotherapy & Psychodiagnosis

VOLUME 13
2012-2013

William T. Tsushima, Ph.D., ABMPP (Editor-in-Chief)
Vincent G. Tsushima, Ph.D., ABMPP
Kenneth N. Anchor, Ph.D., ABMPP
Jeffrey T. Barth, Ph.D., ABMPP

Printed in the United Sates of America

Advances in Medical Psychoterapy and Psychodiagnosis

Volume 13 2012-2013

TABLE OF CONTENTS