

CLINICAL SCIENCE

Society for the Science of Clinical Psychology Section III of the Division of Clinical Psychology of the American Psychological Association



Developing clinical psychology as an experimental-behavioral science

Newsletter

Winter 2007 Issue

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Clinical Science is published as a service to the members of Section III of the Division of Clinical Psychology of the American Psychological Association. The purpose is to disseminate current information relevant to the goals of our organization.

Feature Articles may be submitted to the editor via e-mail. They should be approximately 16 double-spaced pages and should include an abstract of 75- to 100- words.

Brief Articles may also be submitted, and should also include a 75- to 100-word abstract. All articles should be submitted as an attachment to an e-mail and formatted according to the *Publication Manual of the American Psychological Association, 5th edition.*

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Articles published in *Clinical Science* represent the views of the authors and not necessarily those of the Society for a Science of Clinical Psychology, the Society of Clinical Psychology, or the American Psychological Association. Submissions representing differing views, comments, and letters to the editor are welcome.

President's Column:



Daniel N. Klein, Ph.D. Stony Brook University

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It is an honor to serve as President of SSCP. During the past year, I've had the privilege and pleasure to serve on the SSCP Board as President-Elect and to work with President Antonette Zeiss, Past-President Jack Blanchard, Secretary/Treasurer Denise Sloan, and Division 12 Representative David Klonsky. Jack and Denise rotated off the board in January after many years of dedicated service to the organization, and they will be greatly missed. I would also like to welcome our new President-Elect, Lee Anna Clark, and Secretary/Treasurer, Elizabeth Hayden, who have quickly stepped into their new roles and are making the transition seamlessly.

In this column, I will take the opportunity to provide an update on the state of the organization, its ongoing activities, and issues of concern to the membership. In particular, I will report on recent developments in training psychologists for prescription privileges, an issue that has been of considerable interest to many members and has significant implications for our field.

Update on Recent Activities and Issues

SSCP's mission is to affirm and promote the integration of clinical science and practice and the ideal that scientific principles should play a role in training, practice, and health and mental health policy. The organization serves this mission in a variety of ways. First, we are involved in the programming at the annual meetings of both the American Psychological Association and the American Psychological Society. Under the leadership of the past several Presidents, the role and visibility of clinical science within APS has grown, with a number of superb invited presentations and a growing number of outstanding graduate student posters. Currently, the clinical track of the Program Committee consists of a representative from SSCP and a representative from the Academy for Clinical Psychological Science. The next APS annual meeting in May in Washington, D.C., will feature invited addresses by Edna Foa, Susan Nolen-Hoksema, and Daniel Pine. In addition, there will be a poster session for graduate students to present their research, and one of the presenters will receive a graduate student research award of \$200.

At the same time, we continue to try to strengthen clinical science programming at the APA annual meeting. At the

APA convention in San Francisco this coming August, SSCP will sponsor an invited address by Susan Mineka, who will receive the 2007 SSCP Distinguished Scientist Award, the SSCP Presidential Address, and a symposium on developmental psychopathology organized by the SSCP program chair, Emily Durbin.

Second, SSCP maintains an active list serv, which has long been one of the most visible and influential, but also controversial, features of the organization. SSCPnet is one of the major sources of on-line communication and discussion in clinical science. It is vibrant and provocative, and has played a critical role in disseminating information and rallying support on important issues (e.g., the procedures in the American Psychologist's review of Scott Lilienfeld's critique of APA's response to the controversial Rind article on the effects of child sexual abuse). Because of the high traffic and occasional ad hominem post, a significant minority of our members (approximately 40% at last count) choose not to subscribe to the listserv. I don't think the fact that many members have opted out of SSCPnet is a major concern, as the listserv is only one of the many ways that SSCP serves it members. However, I do hope that we will continue to work towards maximizing the exchange of ideas and information, while minimizing postings that are uninformative or ad hominem. Michael Miller recently took on the demanding task of administering the listsery, and is working hard to make it better serve our members.

Third, SSCP maintains a web site, which Jack Blanchard updated and greatly improved during the past year. It provides information on the mission and history of the organization; the by-laws; lists of past award winners; announcements and links for employment opportunities; an archive of previous newsletters; links to key documents such as the history of SSCP, Dick McFall's classic *Manifesto*, and the SSCP internship directory; information about membership in SSCP and subscribing to SSCPnet; and a valuable list of clinical science links and resources.

Fourth, the SSCP newsletter, *Clinical Science*, disseminates information about the organization and the field, and includes significant articles addressing key issues (e.g., Dick McFall's article on clinical science training in the last issue; Greg Miller's article on Institutional Review Boards and "mission creep" in the current issue). Editing a news-

letter can be a thankless task. Therefore, I'd like to convey my deepest appreciation to Bill Horan, who has done a wonderful job editing the newsletter during the past year and a half.

Fifth, SSCP maintains, and is attempting to strengthen, its relationships with APS, APA, and APA's Division 12, in order to increase the influence of clinical science on the field. The major link with APS is through the program committee for the annual meeting. The major link with Division 12 is through our representative on the Division 12 Executive Committee, David Klonsky. David has been working closely with Division 12's past and current Presidents, Jerry Davison and Marsha Linehan, respectively. Marsha recently asked David to chair Division 12's standing Committee on Science and Practice, with the aim of making information on research-based treatments more accessible to practitioners and the public. She also appointed David as Chair of the Division 12 Task Force on Enhancing Science-Based Clinical Practice, which will examine ways to increase the influence of clinical science both within the field and the division.

During his Presidency, Jack Blanchard established a formal relationship with the APA Science Directorate, and we now send a liason to their meeting at the APA annual meeting. SSCP also sent an observer to a meeting of the APA's Board of Educational Affairs/Committee for the Advancement of Professional Practice (BEA/CAPP) Task Force to Review the APA Psychopharmacology Curricula and Related Policies (see below). Finally, Sharon Brehm, the incoming APA President, has established a Task Force to review and analyze Institutional Review Board issues faced by psychological scientists. SSCP contacted the chair of the Task Force, who invited us to submit a brief position statement outlining the major issues that we would like the Task Force to consider. We surveyed the membership for input on the issues that we should ask the Task Force to address, and are in the process of preparing a document that will be submitted shortly.

Sixth, graduate students are the lifeblood of our organization. In addition to the graduate student poster presentations at the APS annual meeting, SSCP will continue to provide small grants (typically \$500 for each of five students per year) for dissertation research. SSCP has also developed and periodically updates an internship directory that provides a guide to science based training and research opportunities that can be accessed through the SSCP web site.

Finally, SSCP also recognizes outstanding lifetime contributions to clinical science with its annual Distinguished Scientist Award. The caliber of the nominees is exceptional, and the choice is always difficult. As noted above, Susan Mineka will receive the 2007 SSCP Distinguished Scientist Award for her pioneering work on anxiety disorders. Sue will receive the award and will give an invited

address at the APA meeting.

At this point I am going to shift gears and discuss two issues of concern to the organization and the field. The first is membership; the second is psychopharmacology training for prescription privileges for psychologists.

Membership

One of the pressing challenges facing SSCP is membership. The number of members in SSCP has declined dramatically during the past decade. In part, this reflects a broader trend of declining membership in professional organizations (e.g., this is also a problem for APS, APA, and Division 12). However, it also reflects administrative problems in tracking membership and actively reminding members to renew. For example, at the beginning of 2006, the majority of subscribers to the listserv were not current members of SSCP. Most subscribers had been members at one time, but allowed their membership to lapse, often without being aware of it. Fortunately, thanks to the efforts of Denise, Jack, Toni, Elizabeth, and Michael Miller, we are turning this around. We are now doing a better job informing members when it is time to renew and sending reminders to those who fail to renew in a timely fashion, making the renewal process more convenient by providing the option of paying online with a credit card, and enforcing the requirement that in order to subscribe to the listserv one must be a member.

The size of the organization has obvious implications for our effectiveness in accomplishing our aims. It has a direct budgetary impact, affecting our ability to give awards to graduate students and to send representatives to other meetings. It also limits the number and expertise of members whom we can call upon to provide information and service. Finally, it will ultimately limit our credibility and influence on other organizations. Hence, one of our main challenges will be to continue to rebuild our membership by renewing old members and recruiting new members. Recruiting students is particularly important, as they represent the future of the organization. Hence, I urge members who are faculty in doctoral training programs to tell their students about SSCP and to ask their departments to consider the option of enrolling all the students in the program for only \$7.50 per student.

BEA/CAPP Task Force

There has been a longstanding interest on the part of many of our members in the issue of prescription priviliges for psychologists. In the last part of the column, I will provide an update on recent developments in training for prescribing. (This is the same update that was recently emailed to all members and posted on the listserv).

The Board of Educational Affairs/Committee for the Advancement of Professional Practice (BEA/CAPP) Task Force to Review the APA Psychopharmacology Curricula

and Related Policies has recently proposed revisions to the APA model curriculum for psychopharmacology training and the APA model legislation for prescriptive authority. These proposals were recently made available at http://www.apa.org/ed/graduate/comment review.html, and are open for public comment through April 29, 2007.

The background and issues in the movement for prescription privileges for psychologists were discussed in the Winter 2005 issue of the SSCP newsletter. About 10 years ago, APA developed model curricula for instruction in psychopharmacology (these documents can be obtained on the web at http://www.apa.org/ed/resources.html). The model curriculum for level 1 training consisted of a one-semester course in psychopharmacology at the graduate level. The curriculum for level 2 training was originally designed for licensed psychologists who were collaborating with physicians and other prescribing professionals, but subsequently evolved into a series of modules on pharmacotherapy with specific populations (children/adolescents, older adults, schizophrenia, and mental retardation/ developmental disabilities).

The document on level 3 training was much briefer than for levels 1 and 2, and outlined recommendations for postdoctoral training in psychopharmacology for prescription privileges for licensed psychologists. The level 3 curriculum required a minimum of 300 hours of didactic instruction in a specified list of content areas, and a clinical practicum that required seeing a minimum of 100 patients for medication in both inpatient and outpatient settings and at least two hours weekly of individual supervision. Although the level 3 curriculum was only a model (e.g., there was no mechanism to require training programs to implement this curriculum), it is significant because the model legislation developed by APA to obtain prescription privileges on a state-by-state basis refers to this curriculum. Hence, states that pass such legislation may require prescribers to complete the model curriculum.

Psychologists currently have prescribing authority in two states (Louisiana and New Mexico). A number of postdoctoral psychopharmacology training programs have been established, most of which are not affiliated with accredited universities and involve significant amount of "distance learning". During the past decade, dissatisfaction with the model curricula has grown. In response, APA created a Task Force under the joint auspices of the Board of Educational Affairs (BEA) and the Committee for the Advancement of Professional Practice (CAPP) to review and revise the curriculum. The BEA/CAPP Task Force met twice, in September and November, 2006. I attended the second meeting on behalf of SSCP as an observer.

As I understand it, the greatest dissatisfaction with the curriculum involved the practicum component of level 3 training. Apparently, none of the graduates from any of the

post-doctoral training programs have been able to complete that portion of the model curriculum, largely due to difficulties in finding appropriate supervision.

In addition, there were concerns about a number of other issues, including the following: (a) the level 3 curriculum specified that the provider of the training program must be a regionally-accredited institution of higher learning or another appropriately accredited provider of instruction and training; (b) the level 1 curriculum was outdated; (c) the level 2 curriculum was not seen as useful; and (d) models of professional training have shifted from emphasizing the content that should be taught by the trainers to emphasizing the competencies that should be gained by the trainees.

Members of the Task Force represented a diverse range of perspectives, interests, and constituencies. Although they were in the minority, the participants included several strong and highly credible representatives of a clinical science perspective. There was a strong consensus that training to prescribe should be limited to licensed doctoral-level psychologists. That is, there did not appear to be support for training for prescribing at the doctoral level.

The Task Force agreed on some revisions in the model legislation and recommended a number of significant changes to the model curriculum; some had widespread support and others were compromises between very different and strongly held perspectives. First, it was agreed that the level 1 curriculum should be updated. Second, the level 2 curriculum was eliminated since much of it was already incorporated in level 1 and the envisioned model of training for collaborative practice never developed. Third, prerequisites for coursework prior to admission to post-doctoral training programs for prescription privileges were eliminated, but the number of didactic hours of instruction in the post-doctoral training program was increased from 300 hours to 400 hours. Fourth, the level 3 curriculum was organized around a competency model of training and evaluation, in which trainees are required to demonstrate competence in a variety of specified areas (e.g., physical exam, review of systems, medical history interview, ordering and interpreting laboratory tests, etc.). Fifth, the requirement that post-doctoral training programs must be associated with accredited institutions was eliminated. Instead, programs must demonstrate that they meet a series of requirements for providing an appropriate training experience. Sixth, there was discussion about how much diversity should be required of the postdoctoral practicum training. Some argued that most trainees would continue to practice in their present setting, so diversity beyond that setting was unnecessary, and that if the practitioner changed practice settings, the APA Ethical Principles and Code of Conduct requires that they seek additional training. However, others argued that even if the trainee remained in the same setting, it is likely that

their practice would gradually change as they received more referrals for medication (e.g., their case mix would include more patients with severe mental illness than when their practice was confined to psychosocial treatment).

The most controversial issue concerned the nature and number of hours required for level 3 practicum training. Much of the debate focused on whether or not to require a minimum number of live patients or face-to-face contact hours, and if so, what number is appropriate. Proponents of a required number of patients or contact hours argued that a minimum amount of hands-on experience is essential for adequate training and evaluation; opponents were concerned that there is no rational basis for choosing a particular minimum, and that any specific number of hours provides a target for opponents of legislation for prescription privileges.

The Task Force participants agreed to the following compromise. A minimum amount of hands-on experience with live patients would not be required. Instead, training programs would decide how much supervised face-to-face experience with live patients and how much other supervised clinical experience (e.g., with simulated patients) they would require for each of the areas of competency specified in the model curriculum. The training program would then have to persuade a designating body ("designa-

tion" in this context is analogous to accreditation) that their requirements are sufficient.

The Task Force did not address who will be responsible for designating postdoctoral training programs in psychopharmacology for prescription privileges or what the designation process will entail. This is a significant unknown, because the revised model curriculum gives programs considerable freedom with respect to how they can demonstrate that they provide an appropriate training experience, who appropriate faculty are, how they ensure that trainees achieve a minimum level of competence in each area, and how they interpret and evaluate competency in each of the specified domains.

The revised model legislation and curriculum were reviewed by BEA and CAPP in January, 2007. As I noted above, they were recently circulated to all APA boards and committees and posted on the APA web site at http://www.apa.org/ed/graduate/comment_review.html for public comment for a 90-day period (through April 29, 2007). I strongly encourage SSCP members to review the proposed changes in the model legislation and curriculum and express your opinions. It is expected that the Task Force will meet for a third time in May to respond to comments and revise the documents. The final documents will then be submitted to the APA Board of Directors in June and to the APA Council in August.

2007 SSCP Distinguished Scientist Award

Dr. Susan Mineka of Northwestern University will be the recipient of the Distinguished Scientist Award. Over the course of her career, Dr. Mineka has made many significant contributions to theory and research on the origins and maintenance of fear and anxiety disorders. Her early studies with primates on vicarious learning in the acquisition of phobic responses and on the role of control in the development of fear have become classics. More recently, Dr. Mineka has published a number of major theoretical papers on the role of conditioning in fear and anxiety disorders and on comorbidity and personality in the emotional disorders. In addition, she is one of the leading investigators in the area of attentional and cognitive biases in the anxiety disorders. Dr. Mineka will receive the award and give an invited address at the 2007 annual meeting of the American Psychological Association in San Francisco in August.

Feature Article:



Asking Too Much of Institutional Review Boards*

Gregory A. Miller

University of Illinois at Urbana-Champaign & University of New Mexico

Consider some premises: (1) Unfettered inquiry is fundamentally important to scholarship and to the many public benefits that quality scholarship brings. (2) Ethical treatment of subjects in human research is imperative, common, and sometimes inconvenient. (3) Serious abuse happens but is very rare. (4) Detecting nonsalient events, with high sensitivity and high specificity, can be more difficult when base rates are low. On these grounds alone, we know that we will have a difficult time establishing procedures for scholars, and for those who regulate them, that both maximize protection of subjects and minimize interference with scholarship. It is guite likely that we will create rules and procedures that most of the time appear to be a waste of resources - regulating common, innocuous activities in order to prevent or detect uncommon, harmful activities. Indeed, if Institutional Review Board (IRB) efforts routinely revealed unethical scholarship, something would be terribly wrong. That most IRB-related work appears unnecessary is ethically very reassuring.

Work on clinical decision-making tells us that judges will (and probably should) alter their decision thresholds based on perceptions of base rates. Thus, a sense that federal regulators have become more willing to "invoke the death penalty" (shutting down virtually all human research indefinitely at an institution found to have hosted seriously noncompliant projects, jeopardizing not only careers but millions of dollars in research grants) has spooked scholars and IRBs alike. One result is that many feel that IRBs are suffering from "mission creep", with the implicit assumption that more regulation of more scholarly activity will improve protection of subjects, scholars, and the universities, hospitals, and other institutions that house them.

Widespread perceptions that IRBs are extending their reach beyond their mandates and beyond their resources are fostering considerable discussion about the nature of research, the proper scope of IRBs, and the principles and mechanics of IRB operation. I have participated in conferences sponsored by the University of Illinois Center for Advanced Study (2003, 2005) and the American Psychological Association (2006) as well as in a series of study

groups at the University of Illinois advising campus administration on the nature and operation of our IRB. The resulting advice is cheap and not to date generally followed, but the issues are coming more into focus. Some issues of definition and scope are particularly clear and far from resolved.

A central issue concerns the nature and scope of scholarly activity that IRBs should routinely review and regulate. This issue turns on both a policy question (should IRBs regulate "all research" or only certain kinds of research?) and an abstract question (what counts as "research?"). On the policy question, a university might decide to require that its IRB review "all research". Federal regulators do not require that, but the buzz has been that the feds do unofficially encourage it, putting unstated pressure on institutions to go that route. Anecdotal evidence suggests that the tide has shifted, however, with more institutions opting for what is called a "limited assurance" agreement with federal regulators, with full-blown IRB review covering only federally funded research, rather than a "general assurance", covering all research at the institution regardless of funding source, in part because of issues discussed below about the appropriateness of conventional IRB criteria and procedures for many kinds of scholarly activity.

Given an assumption that IRB regulation is an ethical good, the policy decision that all research should be regulated to IRB standards is appealing. How could one possibly defend applying lower ethical standards to research simply because it does not have federal funding? But the devil is in the assumptions - here, that IRB standards are in some sense higher than those applied in the absence of IRB oversight. There are at least two problems with this. First, the implication is that a single dimension of ethical judgment exists and applies feasibly and sufficiently to all types of research. Second, IRB standards are not the only basis of ethical judgments. Psychologists are generally familiar with the American Psychological Association Ethics Code. It happens that other disciplines have developed formal ethics codes as well, including disciplines not historically seen as within IRB purview, such as ethnogra-

phy and journalism, appropriate to their diverse research contexts. So the argument should not be about whether it is OK to apply to lower standards to unfunded research. A starting point for a good argument would be: what sorts of ethical issues arise in a particular discipline, and how should ethical treatment of human subjects ensue?

Thus, a focus of the current debate about IRBs is whether a single set of standards should apply to all disciplines under IRB purview. Modern IRBs are a recent invention, growing out of the Belmont Report on biomedical and behavioral research, based in part on the Nuremberg Code. (For a good, brief introduction to this history, see www.hhs.gov/ohrp/irb/irb_introduction.htm. The report was prepared in 1978 and accepted in 1979, so one sees either date for it). What came to be known as the Belmont Principles (respect for persons, beneficence toward them, and justice for them) are laudable, but their operationalization might sensibly vary considerably in different contexts. It has been widely noted that the Belmont process never undertook to address types of activity that are quite different from laboratory research, such as anthropology or journalism. Substantial portions of psychology arguably fall outside that tradition as well. The point is not that non-biomedical disciplines are immune from ethical issues but that the culture that has developed around modern IRBs is fundamentally foreign to those disciplines. Predictably, then, recent attempts to bring them under IRB purview have been highly problematic - hence, mission creep is meeting more and more resistance.

This policy question, of whether a single set of review criteria and mechanisms should subsume all research, presupposes a clear answer to the more abstract question of what counts as research. It could be the case, but it is not the case, that relevant federal regulations provide clear guidance on what is research (Title 45 Part 46 of the Code of Federal Regulations, section 102, www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm):

"(d) 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.

"(e) Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity..."

Paragraph (e) says roughly that relevant terms apply to whatever federal regulators regulate, which is a bit circular and begs the question of what falls within what is to be regulated. Paragraph (d) sounds more promising, defining research as "a systematic investigation ... designed to

develop or contribute to generalizable knowledge." Sometimes this stance is summarized in terms of a scholar's intentions rather than "design" of a project. That is, the design follows from the scholar's goals. In any case, this statement is notoriously difficult to operationalize. What are the bounds on the intent of an individual or on the design of a project? For example, when does an intention or a design form? A friend of mine, an ethnomusicologist, studies the role of music in Hispanic culture in the southwest, particularly the role of and implications for young Latinas, of public performances by family-based musical groups. My friend is also a folksinger in her own right, composing and performing music. An important entree into the families she studies is playing music with them. Does she need IRB approval to play music? To play music with people of a certain ethnicity, simply because she has a relevant research interest and might someday channel her experiences into a research product? Does she need IRB approval to make entries in a private journal? To draw on that journal for her published scholarship? These questions might warrant different answers under different circumstances. Part of the difficulty in this example is that there is a continuum from traditional laboratory psychology research, into community psychology, and out beyond psychology altogether.

A particularly important example is journalism. A journalist might or might not be interested in "generalizable knowledge", and that interest might change as an investigation unfolds. Does this activity fall under IRB purview? IRBs sometimes insist on oversight of journalism faculty doing the same work that journalists based outside the academy are not subject to. Among other issues, how does the concept of informed consent play out in journalism? Is a journalist to be stopped from investigating people who do not consent to being investigated? Furthermore, a journalist, like a community psychologist or an ethnographer, may be trying to understand a neighborhood, not an individual. The primary ethical duty may be to the public, rather than to an individual from whom or about whom the journalist is gathering information. That is simply what it means to do journalism. For an IRB to insist otherwise is not merely to bring journalism under its purview, it is to preclude journalism altogether (not a good thing for a free society). This example does not imply that there are no ethical dilemmas regarding protection of individual subjects, but professional journalism has its own code of ethics, painstakingly developed. It is not apparent that IRB culture ought to trump that.

Turning to a clinical example, the Food and Drug Administration approves specific drugs for specific uses but allows physicians to prescribe approved drugs for uses other than those approved, called off-label prescribing. My impression is that physicians generally consider off-label drug administration to their patients to be entirely within the realm of clinical practice, not research in an IRB sense. One could argue that the goal is to treat the patient, not to produce

generalizable knowledge. But if the physician tries something, and it works, so she tries it on 3 other patients, and it works, she might want to publicize her observations. In fact at some point it might unethical for her not to publicize it. The moment she publicizes it, or plans to, does it become research? Does it fall under IRB review? Reasonable people could agree on some examples of such a case, where the answer is "yes" in some cases and "no" in other cases. But in some cases agreement would be difficult, with physicians claiming that the intrusion of an IRB would amount to the IRB practicing medicine, rather than the physician conducting research of the sort that IRBs ought to monitor. There may be ways for an IRB to assert control over such things, but the premise that research has a specific beginning point defined by the intention of the researcher or the design of the research, when publishable research may not have been the initial goal at all, is not viable.

As an example closer to home for SSCP: What if, having seen clients for decades, and having supervised many dozens of others' cases, I decide to write a scholarly paper or book about therapy? Arguably, the clients might suddenly be considered research subjects. Although the book might or might not include some quotes or vignettes for individual clients, let us assume that there would be no identifying information. Even without such material, anything I would say would be influenced by my clients. This would happen in ways that in many cases would not be assignable to specific clients - not only due to my imperfect memory, but due to my perspective being an emergent property of countless clinical experiences. Where does research begin in this scenario? If and when I choose to write about my experiences as a clinician? Or when I began seeing clients years ago? Does it matter whether the book talks explicitly about real individual cases? What if just about composites based on real cases? Based partially on my own cases, partially on hypothetical cases, partially on cases discussed by other authors? Where is the boundary between my work as a clinical scientist doing therapy and my work as a clinical scientist writing about therapy? When should the IRB pass judgment on my work? Federal regulations could be read to mean that the answer is: at the time my intention to attempt to contribute to generalizable knowledge was formed. But it happens that there was no specific moment that it formed and that I had a notion of contributing to the therapy literature before there were modern, post-Belmont IRBs. For a psychotherapist reflecting on decades of professional work, simply writing up those thoughts is not the bulk of the "research" - most of the research was being done when I was working with those clients, my own supervisors and supervisees, and the colleagues I consulted with all those years. The present claim is not that the IRB has no role in such work but that simply that the federal definition of "research" is not viable as a basis for determining IRB purview.

Although the diverse activities of a clinical scientist may not pose as fundamental a challenge to current IRB culture as does journalism, the harsh distinction between research and non-research activities that IRBs try to make does not make sense in clinical science. The claim here is not that IRBs should disappear altogether - only that a sensible application of current policy is not an option. The implication is not that all the activities of clinical psychologists, community psychologists, journalists, anthropologists, or medical clinicians ought to be exempt from IRB review. But different disciplines have different constraints on ethical responsibility, different notions of what constitutes research, and different boundaries, if any, between research and other aspects of the discipline. IRBs cannot allow every discipline to write its own rules, but IRBs have to come to grips with the culture of each discipline, the meaning of research in each, and the relevant ethics. A single standard is not only unappealing, it is not an option.

A tension in philosophy of science is whether one should offer an articulation of some ideal notion of how to do science vs. offer a characterization of how scientists actually do their work. Large portions of scholarly endeavor do not unfold as current IRB culture assumes. The stipulation that, in effect, IRB purview begins when the scholar forms an intention to study human subjects is unworkable in the general case. A scholar typically has a general intention spanning years or decades and may entertain numerous research designs that evolve in parallel, usually based heavily on prior research. There may be no precise starting point for a project. The argument here is not that these factors make IRB purview impossible – only that basing IRB purview on assumptions that do not apply to some types of research creates an unworkable scenario.

Although one of the central debates about IRBs is often framed in terms of whether all research should be subject to IRB review, this is actually not worth arguing about. For reasons just reviewed, a policy that "all research" should be reviewed is simply not meaningful and not workable. In the absence of clear, shared definitions of crucial terms, IRBs will necessarily operate inconsistently, and scholars will necessarily run afoul of what IRBs request. This is not a function of bureaucratic perfidy or scholarly immorality. It is entirely predictable, and unavoidable, despite the best of intentions on all sides.

The IRB should not try to protect my client from the future risk of ending up with a few of his words spoken in therapy appearing in my book some day, nor to protect Aristotle from discussion by a classical scholar, nor to protect Richard Nixon from the Washington Post. Possibly issues of consent and IRB oversight arise when I write the book, but not when I am doing the therapy. Even regarding the book, I could argue that the unit of analysis is not an individual client, but a particular type of psychopathology I faced in a number of clients, or a dynamic that arose

sometimes between client and therapist, or an issue I repeatedly confronted about the role of a therapist. If my focus is not on individual clients, if that is not the unit of analysis, who could I meaningfully get consent from?

The expansion of IRB reach beyond biomedical research into fields not on the table when relevant principles and practices were developed brings great burdens not only on researchers but on IRBs, diverting resources from oversight of research that does warrant close scrutiny. The same damage is caused by the expansion of the types of judgments IRBs are now being asked to make, such as about the value of the research, which in most cases IRBs lack the expertise and time to do. Having sat on a campus IRB and having chaired a departmental review committee, I have seen how a shortage of staff resources, in the face of escalating and sometimes inappropriate performance demands, undermines an operation that, as argued above, is already not viable on a priori grounds. Understandable institutional temptations to centralize and standardize are exactly the wrong strategy. We need clearer definitions (not only of "research" but of "harm" and "risk", for example, which are not defined in 45 CFR 46) and better appreciation for the differentiation of disciplines potentially relevant to IRB oversight. That has to be achieved at a national level, not left to each IRB to fumble with.

Most ironically, there is virtually no research available on the actual behavior of IRBs. We know very little about how IRBs set thresholds for "minimal risk" or "discomfort"; about typical numbers of protocols reviewed, turnaround time, approval rates; or especially how effective the IRB system actually is in protecting subjects. Recent national conferences have sounded the alarm. Some thoughtful reports on various sides of the issues have recently appeared, for example a report by the American Association of University Professors (www.aaup.org/AAUP/About/committees/ committee+repts/CommA/ResearchonHumanSubjects.htm ?wbc_purpose=Basic&WBCMODE=PresentationUnpublished). The Journal of Empirical Research on Human Research Ethics (www.jerhre.org) is a very promising new venue. An upcoming conference (www.primr.org/education/ 2007 SBER/overview SBER 07.html) will be devoted

solely to social, behavioral, and educational research, with some emphasis on how work in these disciplines differs from the primarily biomedical model of traditional IRB review.

The temptation for the individual scholar is to see this problem of IRB mission creep as merely an isolated hassle with which one can hopefully minimize engagement. But if we do not jump in and contribute, there is little chance that the results of other forces in this continuing evolution will be favorable to our work or to our subjects. For example, there is some talk of universities and medical centers outsourcing IRB review to commercial entities. It is difficult to imagine that that would be an advance for academic freedom. It is essential that active scholars participate on IRBs and work to improve them, from inside and outside.

*Acknowledgments:

I appreciate Dan Klein's invitation to comment on the recent crescendo in debates about the scope of IRB regulation of scholarship. I thank my fellow members of the University of Illinois Center for Advanced Study Steering Committee: E.M. Bruner, N.C. Burbules, L. Dash, M. Finkin, J.P. Goldberg, W.T. Greenough, C.K. Gunsalus (chair), & M.G. Pratt. Also due thanks are Stephen Breckler and Ivor Pritchard for insightful consultation. Some of the points made here draw from the collective work of the Steering Committee:

Gunsalus, C.K., Bruner, E.M., Burbules, N.C., Dash, L., Finkin, M., Goldberg, J.P., Greenough, W.T., Miller, G.A., Pratt, M.G., Iriye, M., & Aronson, D. (2005). The Illinois White Paper - Improving the system for protecting human subjects: Counteracting IRB "Mission Creep". In C.K. Gunsalus (Ed.), Human subject protection regulations and research outside the biomedical sphere. Urbana, IL: University of Illinois Center for Advanced Study, available at www.law.uiuc.edu/conferences/whitepaper/whitepaper.pdf.

Gunsalus, C.K., Bruner, E.M., Burbules, N.C., Dash, L., Finkin, M., Goldberg, J.P., Greenough, W.T., Miller, G.A., & Pratt, M.G. (2006). Mission creep in the IRB world. Science, 312, 1441.

Congratulations to Our New SSCP Officers!

Lee Anna Clark

University of Iowa

President-Elect

Elizabeth Hayden

University of Western Ontario

Secretary/Treasurer

Both began their terms in January, 2007

Division 12 Update

E. David Klonsky Stony Brook University

In January 2007 Marsha Linehan took over as president of Division 12. Dr. Linehan has developed several initiatives with direct relevance for SSCP. A Task Force on Strengthening and Promoting Clinical Science has been created. The task force has a dual charge: to develop recommendations for promoting science-based clinical practice and to determine how to make Division 12 a home for clinical scientists. In addition, Dr. Linehan has charged the standing Committee on Science and Practice to develop an updated, online list of research-supported treatments. Division 12 receives regular requests for copies of the

empirically-supported treatments list that was published several years ago. An updated, web-based version would facilitate the dissemination of this information to practitioners and consumers. Finally, an effort to clarify the identity of Division 12 is underway. This initiative is being chaired by Linda Sobell. Key issues being addressed include: ensuring that section members feel an identity within the division, finding common ground and partnering with other divisions, and formulating a perspective on what constitutes evidence-based practice.

2007 SSCP Dissertation Award Recipients

Marcel Bonn-Miller

University of Vermont
Mentor: Michael Zvolensky

Frequency of Marijuana Use and Anxious and Fearful Responding to Bodily Sensations: A Laboratory Test

The proposed study represents an effort to better understand the relation between frequency of marijuana use (non-use, low regular use, and heavy regular use) and anxious and fearful responding to bodily sensations among 93 community-recruited adults within the context of a biological challenge paradigm. Based upon anxiety-marijuana integrative models, it is hypothesized that heavy marijuana users will report greater levels of (a) anxiety focused on bodily sensations and (b) intensity of endorsed panic attack symptoms compared with non-user and low regular user groups; the non-user and low regular user groups are expected not to differ from one another. Additionally, it is expected that heavy marijuana users will show a greater desire to avoid *future* exposure to somatic perturbation post-challenge than the other two groups; again, no differences in terms of avoidance are expected between the non-users and light-users (those that use marijuana regularly but not heavily). Finally, in terms of physiological responding, it is expected that all three groups will show similar levels of respiration rate during the challenge, but that the heavy marijuana user group will show greater heart rate reactivity compared with the other two groups, which will not differ from one another. Overall, it is expected that the present findings will advance understanding of the potential linkage between specific types of marijuana use and anxious and fearful responding to bodily sensations, and as such, represent an emerging, yet largely historically unexplored, laboratory model of panic vulnerability.

Valerie Grant

Dalhousie University Mentor: Sherry Stewart

Emotional Antecedents of Alcohol Cognitions & Consumption in Drinkers with Coping-Anxiety, Coping-Depression, &/or Enhancement Motives

Internal motives for drinking are associated with heavy and/or problematic alcohol consumption (Cooper, 1994), thus it is important to determine the unique triggers of alcohol cognitions or consumption among drinkers with these motives. The

aim of this research is to determine the emotional antecedents of alcohol cognitions and consumption in drinkers who report that they drink to cope with anxiety (CM-anxiety), to cope with depression (CM-depression), and/or to enhance positive feelings (EM). Study 1 will determine the factor structure and test-retest reliability of the Modified Drinking Motives Questionnaire – Revised (Modified DMQ-R; Blackwell, 2003), which separates coping motives into two anxiety-and depression-management subtypes. Study 2 explores the impact of musically induced positive and anxious mood on alcohol cognitions in CM-anxiety and EM drinkers. The hypotheses are that anxious, but not positive, affect will trigger alcohol cognitions in CM-anxiety participants and that positive, but not anxious, affect will trigger alcohol cognitions in EM participants. Study 3 investigates the genuine emotional antecedents of actual drinking behaviour over 21 days. The hypothesis are: (a) participants who score higher (vs. lower) on the EM subscale (of the Modified DMQ-R) will have a stronger positive relationship between daily positive mood and subsequent alcohol consumption; (b) participants who score higher (vs. lower) on the CM-depression subscale will have a stronger positive relationship between daily depressed mood and subsequent alcohol consumption; and (c) participants who score higher (vs. lower) on the CM-anxiety subscale will have a stronger positive relationship between daily anxious mood and subsequent alcohol consumption.

Brant P. Hasler

University of Arizona Mentor: Richard Bootzin Diurnal Rhythms in Co-Sleeping Couples

The processes underlying emotion regulation are highly relevant to mental health. Although the understanding of the neurophysiological underpinnings of emotion continue to progress, much remains to be elucidated. Furthermore, the regulation of mood, an affective phenomenon related to emotion in which the subjective feeling is the primary component, remains even less understood. Notably, investigations of the role of circadian processes in mood have yielded particularly intriguing results. A number of studies have noted the same pattern: that self-reported positive affect varies according to a diurnal (daily) rhythm, while self-reported negative affect does not. These differences may reflect distinct underlying motivational systems. In addition, a complete account of affect regulation requires attention to how individuals influence one another's mood. One might expect individuals in pair-bonds to have a relatively large mutual impact on their moods; however few (if any) studies have examined how dyad members might impact one another's mood via effects on the underlying physiology rather than via psychological mechanisms. In an effort to integrate these two areas of mood regulation, this project will investigate the associations of variations in circadian activity rhythms, sleep, and positive and negative affect in the context of a co-sleeping romantic relationship.

Jill M. Holm-Denoma

Florida State University
Mentor: Thomas Joiner

The Latent Structure of Restrictive Eating Behaviors: Taxometric Investigation and Construct Validation Using Genetic and Personality Indicators

Although the DSM-IV assumes that mental disorders are categorical in nature, little empirical examination has evaluated whether this assumption is true. Some previous investigations of eating disorders have provided empirical support for the existence of eating disordered taxa, although others have failed to replicate the pattern. In this study, the latent structure of restrictive eating behaviors will be examined using taxometric analyses (e.g., MAXEIG and MAMBAC) in clinical (N=204) and non-clinical (N = 2030) samples of women. If taxonic results emerge as predicted, construct validation assessments will be conducted using personality (e.g., perfectionism, obsessionality) and genetic (serotonin transporter gene short allele, 5HT2a receptor gene A allele) indicators of anorexia nervosa. If continuous results emerge, latent class analysis and latent class profile techniques will be used to form clusters of individuals with similar levels of symptomatology. Patterns of personality and genetic variables will be examined in relationship to the identified clusters. Results will have implications for theoretical development, enhanced understanding of etiology, improved identification of powerful indicators, and therapeutics.

Peter D. Yeomans

Drexel University Mentor: James Herbert

The effect of Posttraumatic Stress Disorder Psychoeducation on the Nature and Severity of Traumatic Stress Symptoms in a Burundian Sample

The diagnosis of Post-Traumatic Stress Disorder (PTSD) has been increasingly applied to diverse cultural settings, even as the validity of the construct sparks controversy and debate. Argument continues over whether the symptoms of PTSD are primarily driven by biological response or cultural factors. Given evidence for the suggestive and iatrogenic effects of some PTSD treatment methods and other interventions, as well as the theoretical support for the presence of social influences germane to cross-cultural research and treatment, it is proposed that the inclusion of PTSD psychoeducation in non-Western pre-industrialized settings may diminish otherwise beneficial treatment effects. Additionally, other forms of exposure to Western trauma discourse may also contribute to symptom presentation, as previous studies have found that exposure to such discourse was predictive of PTSD symptom severity. The proposed project will draw on an indigent, rural Burundian sample, and will use an experimental design to examine the influence of PTSD psychoeducation on the nature and severity of traumatic stress symptoms reported. Participants will be randomized into three conditions: workshop with psychoeducation, workshop without psychoeducation, and a waitlist control. It is hypothesized that participants in the psychoeducation condition will experience a lesser reduction in PTSD symptoms relative to other conditions, and that general anxiety, depression, and somatization symptoms will decrease in both active conditions, relative to the wait list control group. Secondary hypotheses predict relationships at baseline between prior exposure to Western trauma models and the nature and severity of posttraumatic stress symptoms.