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PUNCTUATED EQUILIBRIUM, MORAL PANICS AND THE ETHICS REVIEW PROCESS

ABSTRACT. A review of the literature and ethnographic data from Australia, Canada, New Zealand, the United States, and the United Kingdom on the research ethics review process suggest that moral panics can become triggers for punctuated equilibrium in the review process at both the macro and microlevel, albeit with significantly different levels of magnitude and impact. These data suggest that neither the development of the ethics review process nor the process itself proceeds gradually, but both are characterized by periodic major shifts evoked by particular events or situations that result in varying levels of moral panic. One way to deal with this moral panic is to increase the regulation of research and the depth or intensity of the scrutiny of applications under ethics review. Moral panics at the macrolevel influence those at the microlevel and, if the moral panic evoked at the local or microlevel is not satisfactorily resolved, it will evoke action at a higher level. Understanding the evolution of research ethics review processes from this perspective might help make actions by ethics committees and policy makers more understandable and help explain why attention to research ethics are heightened at particular points in time. It may also provide a basis for developing recommendations for adaptations to the ethics review process and policy at both the local and macrolevel.

KEY WORDS: Australia, Canada, New Zealand, research ethics review process, United Kingdom, United States

INTRODUCTION

In 1972 Eldredge and Gould proposed the revolutionary and controversial concept of punctuated equilibrium to explain apparent breaks in the paleobiological or archaeological record. They suggested that evolution did not occur gradually and thus these breaks were not breaks at all, but the result of radical changes that resulted as a response to catastrophic events. In 1988 Gersick (1988) used the concept to explain the evolution of work in work teams. She suggested that work teams did not work at a steady state, but that there were identified periods when there was a rapid acceleration in the work of the team. Later Romanelli and Tushman (1994) and others tested Gersick's analogy and demonstrated that there was empirical evidence for punctuated periods of transition in work groups and organizations.

Chalmers and Pettit (1998) have suggested that the evolution of the research ethics review process has been a result of periodic crises or controversies or what they call the "controversy machine." Van den Hoonaard

(2001) talks about evolution of the ethics review process using Cohen's (1972) concept of "moral panic." These three concepts: punctuated equilibrium, the controversy machine or crisis cases, and moral panic, can be used to understand both the evolution of the ethics review process at the macro level and, at the microlevel, the process of review, in particular, meetings where the purpose is to review applications submitted for ethics approval. In both cases we can see a pattern that demonstrates that the ethics review process is not one of 'gradualism,' but one that is punctuated. These spikes in the process are in response to crises or controversies that result in a kind of moral panic that is addressed by making changes in the process or the pace of the work. These changes are more marked at the macrolevel, but no less important, at least for individual researchers and specific reviews, at the microlevel. In fact, these two levels are not mere reflections of one another, but are intimately inter-related. This pattern, like the one suggested by Eldrege and Gould, is not regular with periods of stasis and change, but is also marked by what one of my informants suggested were periods of 'static' where minor adjustments occur.

The idea that the ethics review process can be understood from the perspective of punctuated equilibrium brought on by moral panic is based on data from an international ethnographic research project on ethics and the ethics review process as culture and cultural process, making the use of the punctuated equilibrium analogy particular apt. The work draws on multiple sources of data, in particular observations of 28 ethics committees in five countries (Australia = 12, Canada = 2, New Zealand = 3, UK = 4, USA = 7) in the process of reviewing ethics applications; formal and informal interviews with key informants (researchers – students and experienced, committee members, policy makers, many who fit in more than one category); participation in workshops, meetings and forums; and analyses of the relevant literature and public policy documents. Formal interviews involved 189 people, with some people interviewed more than once formally and/or informally. The data come from five countries: Australia, Canada, New Zealand, the United Kingdom, and the United States of America. The idea of ethics meetings fitting a punctuated equilibrium model of group process came out of a discussion with one key informant who suggested that what I was describing when I described the patterns I saw in the meeting process fit this model. The idea of static in the system, rather than periods of absolute stasis, and that this static evoked minor changes, came out of a conversation with another key informant when I described how I thought the punctuated equilibrium model or analogy

might fit the evolution of the ethics review process at both the macro and microlevel.

PUNCTUATED EQUILIBRIUM AND GROUP PROCESS

Gersick (1988) used the punctuated equilibrium analogy to present the patterns of activity associated with work teams organized to accomplish a specific task over a period of time, not the work within a specific meeting. She found that periods of heightened activity were “triggered more by members’ awareness of time and deadlines than by completion of an absolute amount of work in a specific developmental stage” (Gersick, 1988, p. 9). She noted that the pattern across groups was highly consistent. Every group began with a distinctive approach to the work and maintained that pattern for a period of time, but then some factor evoked a quantum change or changes that resulted in dramatic progress in their work only to then fall into another pattern, a period of what she calls stasis, which only changed again if another stimulus, like time pressure and an approaching deadline, evoked another period of enhanced activity. Gersick’s work deals with teams that function over a period of time that involves multiple meetings, but despite variations in the length of time for completion of a project the overall pattern persisted.

Romanelli and Tushman’s (1994) work on organizational transformation highlights that the periods of apparent stasis are perhaps better identified as periods of relative stability. During these periods there are small changes, but they do not accumulate to the level where they produce a fundamental change. This equates with what my informant called ‘static.’ Revolutionary or fundamental change results when some force, like some change in the environment – a change in leadership, work strategy, structure or power distribution, disrupts or challenges the established pattern and sets the basis for a new pattern. They note that “according to the punctuated equilibrium model, radical and discontinuous change of all or most organizational activities is necessary to break the grip of strong inertia” (Romanelli & Tushman, 1994, p. 1143). In other words, these bursts of activity or change are not only common; they are important and necessary. Based on their study of 25 organizations they concluded that organization transformations commonly fit the patterns described by the punctuated equilibrium model (analogy) and these transformations were generally associated with events or people that produced some important change in what we might identify as the social and cultural environment.

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MORAL PANIC

Moral panic results from an event, episode, person or group of persons that poses a perceived threat to societal values and interests (Cohen, 1972, 1980). The nature of this

is presented in a stylized and stereotypical fashion by the mass media; the moral barricades are manned by editors, bishops, politicians and other right-thinking people; socially accredited experts pronounce their diagnoses and solutions; ways of coping are evolved or (more often) resorted to; the condition then disappears, submerges or deteriorates and becomes more visible. Sometimes the object of the panic is quite novel and at other times it is something which has been in existence long enough, but suddenly appears in the limelight. Sometimes the panic passes over and is forgotten, except in folklore and collective memory; at times it has more serious and long-lasting repercussions and might produce such changes as those in legal and social policy or even in the way the society conceives itself. (Cohen, 1980, p. 9)

In relation to ethics review these events are often the publicized scandals in the mass media and professional texts on research and research ethics, including those raised in ethics guidelines or regulatory documents. The groups include researchers who are perceived to have behaved badly (e.g., not followed guidelines or ethics review processes and those who have personally profited from their research by using research populations as a ‘means to an end’) and, in particular, drug companies. In fact, in my research there is a clearly articulated demonization of drug companies.

As van den Hoonaard (2001, p. 25) points out, “moral panic occurs throughout the research-ethics review.” He quotes a member of an ethics committee: “Today’s academic research environment, with its public (and not public) scandals, provides a strong incentive toward regulation and monitoring” (van den Hoonaard, 2001, p. 25). Following Cohen, van den Hoonaard goes on to say that “moral panics involve exaggeration of harm and risk, orchestration of the panic by elites or powerful special-interest groups, the construction of imaginary deviants, and reliance on diagnostic instruments” (van den Hoonaard, 2001, p. 25). The elites include, among others, the President of the United States (Clinton, 1994) and the special interest groups include ethics committees and policy developers along with such groups as animal rights activists, community organizations, and members of special disease and illness organizations. In fact, ethics committees have become powerful elite social groups in that they are the final arbitrators of whether or not a research project can be conducted. Whether or not they are officially identified as surrogates for the community, they have nonetheless become powerful community moral gatekeepers.

THE CONTROVERSY MACHINE AND CRITICAL/CRISIS CASES: THE
MACROLEVEL

The cases that drew particular attention to research-related ethical issues in the public and professional domain and had an impact on the development of research ethics and the ethics review process have been called by various names: critical cases, crisis cases, pivotal cases, turning points, scandals (Nicholson, 2003; Pettit, 1992), critical moments (Putney & Gruskin, 2002), etc. In relation to the ethics review process at the macro level we can see the punctuated nature of its evolution by exploring what I call the “obligatory history” chapter or section common to most texts on research ethics and many public documents related to the ethics review of research. The obligatory history involves the presentation of a series of cases that highlight periods of ethical (or moral) crisis in society (see Table I). The same cases are cited repeatedly and this body of cases is relatively small in relation to the amount of research conducted.

The majority of the cases are associated with medical research, but there is also a core body of commonly cited cases from the behavioral sciences, particularly psychology. Historically, few cases in this literature are primarily associated with the social sciences, such as sociology and anthropology. The most commonly cited cases across all the literature on research ethics are the same group of cases from 40 or more years ago and are primarily associated with World War II and the 1960s (see Table I). Publications from particular countries then add at least one pivotal local case. In the last decade one case has been added to the commonly cited pantheon. That is the case of Jesse Gelsinger, a young man who died while involved in a genetics related clinical trial (Gelsinger, 2003; Savulescu, 2002). Some discipline specific literature includes a more recent case or two, but these cases are often not well known outside that discipline. In anthropology these include, for example, the *Darkness in El Dorado* controversy based on a book published in 2000 (Tierney, 2000) criticizing Napoleon Chagnon’s and his colleagues’ work among the Yanomami beginning in the 1960s and Kennewick Man, a controversy over ownership of a prehistoric skeleton uncovered in Washington State in the USA in the mid-1990s (e.g., Fluehr-Lobban, 2003a, 2003b).

The first critical or crisis ‘case’ regularly referred to is the World War II Nazi experiments and the Nuremberg trials. They resulted in the Nuremberg Code, often erroneously cited as the first research code of practice. The international acceptance of this Code is viewed as a pivotal event in the institutionalization of the ethics review process.

TABLE I
 Examples of some commonly cited critical cases in medical and behavioral/social science research and key responses

Commonly cited ^a	Study	Description	Country	Time period
<i>Medical research</i>				
x	Nazi medical experiments		Nazi Germany	Late-1930s to mid-1940s
x	Radiation experiments	Exposure of soldiers and patients to radiation	USA, Australia (Britain)	1940s and 1950s
	Jewish Chronic Disease Hospital cancer study	Injection of live cancer cells into 26 chronically ill, elderly patients	USA	1963
	Willowbrook	Study of the natural history of hepatitis among children in an institution	USA	1963–1966
	National Women's Hospital cervical cancer study ("The Unfortunate Experiment")	Study of the natural history of cervical cancer	New Zealand	1966 Cartwright Inquiry 1988
x	Tuskegee syphilis study	Long-term effects of untreated syphilis	USA	1932–1972 Presidential public apology 16 May 1997
x	HIV/AIDS research in developing countries Jesse Gelsinger	A wide range of studies involving drug trials Gene therapy trial where the person died	Multiple USA	1990s 1999

TABLE I
(Continued)

Commonly cited ^a	Study	Description	Country	Time period
	Ellen Roche	Asthma study using induced symptoms in a healthy volunteer who died	USA	2001
<i>Social and behavioral science research</i>				
x	Wichita Jury Study	Study of juries' decision making processes	USA	1950s
	Milgram	Use of sham shocks to a confederate learner to study behavioral obedience	USA	1960–1964
	Stanford prison study (Zimbardo et al.)	Simulated prison	USA	1960s
x	Project Camelot and Thailand controversy	Field research to study conditions related to internal conflict	USA (Latin America and Southeast Asia)	1960s (aborted before it began)
x	Laud Humphrey's "tea room trade" study	Disguised participant observation – Study of homosexual behavior in public toilets	USA	1960s
	Pseudo-patients in a mental hospital (Rosenbaum)	Disguised participant observation – study into the effects of psychiatric labeling	USA	1970s
x	<i>Darkness in El Dorado</i> (Tierney)	Allegations of misconduct by anthropologists Chagnon and Neel in relation to research among the Yanomami beginning in the 1960s	USA	1990s

TABLE I
(Continued)

Commonly cited ^a	Study	Description	Country	Time period
	Kennewick Man	Dispute over ownership and research access to skeletal remains uncovered in 1996 in Washington State involving the Native American Graves Protection and Repatriation Act (NAGPRA)	USA	1996
	Russel Ogden	Challenge to absolute confidentiality originally related to research on assisted suicide/euthanasia	Canada (Britain)	mid to late 1990s
<i>Responses</i>				
x	Nuremberg Code		International	1946
x	First Declaration of Helsinki		International	1964
	Institution of research ethics review committees		Multiple	1960s
x	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	Produced the Belmont Report published in 1979 and made recommendations in relation to reviews	USA	1974-1981
	Institutional closures		USA	1990s
	Revision of ethics review guidelines/regulations		Multiple	1990s

^a Commonly cited across the literature of most disciplines.

PUNCTUATED EQUILIBRIUM, MORAL PANICS AND THE ETHICS REVIEW PROCESS

What is interesting is that in most discussions about the Nuremberg Code and the Helsinki Declaration that followed in 1964 and the resulting institutionalization of international codes of practice for medical experimentation is that they almost always focus exclusively on the human medical experiments in Germany during the war. Until very recently few included discussions of research conducted in or under the sponsorship of other countries, including the USA, Australia, Britain, Russia, and Japan. For example, only in the more recent literature are references to such things as the radiation experiments included.

CRITICAL CASES AND PUNCTUATED EQUILIBRIUM: MACROLEVEL

A review of commonly cited cases after this war-related peak of activity indicates that they fall within particular blocks of time: the mid-1960s, late 1970s and early 1980s, early 1990s, and again in the late 1990s with the literature on these latter cases rolling over into the early 2000s (see Table I).

The peak in the mid-1960s coincides with the institution of, or push towards, the institutionalization of the ethics review process in the United States and Australia in 1966 and Britain in 1967. The institution of ethical guidelines in Canada occurred in 1976, which coincides with the beginning of the 1970s peak, with the current policies formulated in 1998, coming into effect in 2001. New Zealand officially entered the institutionalization of ethics committee review domain following the 1987 Cartwright Inquiry Report into the National Women's Hospital cancer study. The peak dates are related to the formal institution of ethics review processes at the national level or some major revision in national guidelines. In all of these countries there was some system of ethics review in place for medical research prior to these dates, but the policies and procedures were generally not institutionalized at the national level.

In addition to the pivotal crisis cases, at least one other factor needs to be considered in relation to this pattern. In both the 1960s and the 1990s there was a move towards subjecting all research, not just medical research, to the ethics review process. In the USA and elsewhere this was often linked to access to federal research funding. No review; no federal funding to the institution.

Chalmers and Pettit (1998) talk about the "evolution of an ethic among those conducting research" (p. 79). They note, and many others would seem to agree, that the whole ethics review process has been driven by the "controversy machine." Public scandals, generally reflecting key

social issues at that time, lead to more rigorous surveillance and may evoke changes in the process. They outline this evolutionary turn in the following way:

Some research is pursued in an ethically dubious fashion, or with ethically deplorable results. The whistle is blown by an insider, or a newspaper or community group comes to learn by another means what is happening. There is a public scandal, leading to popular demand that something be done to make sure this never happens again. The professional bodies, or other authorities, respond to the demand by taking appropriate action, or at least action accepted as appropriate. Things quiet down, but then, perhaps years later, another scandal is uncovered and the process runs its course once more. (Chalmers & Pettit, 1998, p. 79).

As this paragraph demonstrates, Chalmers and Pettit's description is consistent with Cohen's description of moral panics and their sequelae. There is a dramatic event followed by public disquiet, often played out in or exacerbated by accounts in the media. Then there is some form of moral enterprise that results in the mobilization of the control culture (Cohen, 1980, p. xxiv).

Although there are often regular 'scandals' and crisis cases, most do not evoke major change. Instead, they create 'static' in the system that may result in minor or local changes, but not significant changes in the whole system. However, these bits of static can accumulate to the point where they create as sense of irritating 'noise' in the system that must be addressed. In recent years some of that noise has been coming from non-medical researchers who have had various problems with the review system, in particular problems related to the fact that the review system grew out of medical research and scandals or critical cases related to medical research and, thus, the review process presents problems for them. However, the problems are far more complex than suggestions that the review process is not oriented to other kinds of research. One part of this complexity involves the ethical concerns and imperatives for researchers conducting research that uses other paradigms. The review process either does not deal with their ethical concerns or pressures researchers to engage in practices they view as unethical and, thus, it evokes a sense of moral panic (and outrage) (American Association of University Professors, 2001; Fitzgerald, 1994; Israel, 2004; Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC), 2004).

MORAL PANIC AND PUNCTUATED EQUILIBRIUM: MACROLEVEL

The most notorious trigger for moral panic in relation to research ethics review is, of course, the Nazi experiments of World War II. At that point

the moral outrage was towards a social 'other.' As noted above, presentations on the institutionalization of the ethics review process, the Nuremberg Code, the Helsinki Declaration, and related efforts towards the early regulation of medical research often conspicuously leave out references to research conducted during this period by Japan and the Allied nations that are by today's standards every bit as reprehensible (Nie, 2003, 2004). In fact, much of the moral outrage in relation to the Milgram research was not because the participants might have been harmed, but that the research revealed that everyday, basically good people (our peers) could under certain conditions behave in ways unfathomable to most people living in comfortable circumstances was just not acceptable. The idea that the 'other' could be 'us' was too distressful and people did not want to hear about such things (see also Nie, 2004). When all this was reinforced by the Stanford prison experiment (and the more recent events at Abu Grieb prison), it was just too much to accept so there was a need to demonize someone (create folk devils to use Cohen's term). In this and many later cases, it was people in 'authority' and positions of trust – doctors and researchers and, worst of all, doctors who did research.

This same moral panic helps explain the outrage over Humphreys' (1970) work. Not only did Humphreys make it clear that apparently morally upstanding heterosexual men could participate in an activity that was considered illegal and immoral, sick, but that it was relatively easy to identify the moral peccadilloes of everyday folk. Humphreys' work made people feel not only vulnerable but elevated a sense of distrust of those in authority. People's private lives were clearly not so private after all and anyone could be implicated in what was then considered morally reprehensible behavior. At this time homosexuality was only just beginning to move from a moral deviance explanatory model to a disease model – and both the moral and disease model produced unacceptable products or 'damaged goods' (Philips, 1990).

The moral panic and outrage evoked by these studies and the 'folk devils' (Cohen, 1980) who created them and the other crisis cases, including some from the early to mid-1990s (e.g., Jessie Gelsinger and genetic research, *Darkness in El Dorado* and anthropological and other research among potentially vulnerable populations), and the mass media attention to them resulted in the kinds of responses predicted by Cohen's descriptions of moral panic and folk devils. The responses did not only occur at the local level, but they were taken to the national and, even, international level. Calls for the control of research using a rhetoric of ethics dominated the public media along side of

the other scandals of the day and evoked much attention to the ethics review and oversight of research and a tightening of the 'rules' guiding the conduct of research or at least the rules for evaluating research.

THE CONTROVERSY MACHINE AND CRITICAL/CRISIS CASES: THE MICROLEVEL

The macrolevel and microlevel are interrelated parts of a whole. Many of the critical cases initially became critical cases at the microlevel, within a particular institution. When they were not contained or addressed at that level or there was an information 'leak' that made the cases more public, then they followed a trajectory in line with that described in Cohen's (1980) book and the earlier quote by Chalmers and Pettit. With the help of the mass media to fuel the moral panic, these cases move to the macrolevel. To address the community outrage and moral panic, the government takes action by holding national hearings followed by some change or recommendation for ethics review. The Jesse Gelsinger case in the US (Gelsinger, 2003; Savulescu, 2002) and the cancer study at the National Women's Hospital in New Zealand (Coney, 1993) provide particularly good examples of situations that broke loose from local containment and, with the help of the mass media, became national issues of concern and resulted in action at the national level by the 'moral gatekeepers.'

Thus a case at the local level can escalate to the macrolevel, but the final effect is still at the local level, played out in ethic committees and their responses to the applications submitted to them. Local committees evoke these national cases to deal with local cases or to explain their decisions related to a local case. For example, in one meeting the critical case involving the woman who died in the study involving bronchoscopy was cited to raise a question related to an application being reviewed and the Gelsinger case was cited on several occasions when committees were reviewing information sheets and consent forms. In Cohen's (1980) terms, these cases tend to sensitize people to expect the worst in relation to the applications they review. They develop 'worst case scenarios' and may make their decisions based on these hypothetical possibilities (see also National Research Council, 2003).

This kind of situation can be seen in some committees in the US that were subjected to 'shutdowns' or the threat of the possibility of a shutdown in the 1990s. At the local level there has been an emphasis on 'paper trails' and clear documentation of all decision making. Some

committees tape record the meetings and others use several note takers. The effect of the shutdowns can also be seen in other countries where there is not only knowledge of what happened in the US, but where there has been a 'problem' case where the lack of a paper trail or the fact that there was a paper trail might have been potentially important. In one meeting a member wanted to approach a researcher to discuss the questions raised by the committee. Many committees allow and may even encourage this kind of contact, but not this committee. After much discussion, the committee, clearly influenced by the position of the Chair, would not allow this personal contact because they said they wanted all contacts with the researcher document in writing. One committee clearly had a 'standing policy' or expectation that all researchers would return interview transcripts to respondents. When one applicant apparently indicated this would not be the case for the project being reviewed,¹ one member insisted that the researcher be told the transcripts had to be returned and did so by citing past cases, issues about data ownership, and something the member had recently read that said this was good and standard practice. The argument was presented as a moral argument with one standard for all research involving interviews. When this discussion occurred, the idea of this standing policy helped explain why at the beginning of the meeting I was asked to provide the committee with a copy of my field notes.² Thus, macrolevel panic enacted at the microlevel can affect the development of new (often idiosyncratic) policies and procedures.

On the other hand, local committees have their own folk devils and moral panics. These too sensitize committee members to consider 'worst case scenarios' in their discussions of applications so that a case of moral panic evokes further moral panic. Some committees referred to particular researchers who they saw as having been 'problems' in the past, commonly referred to in one meeting as "*that* researcher." Particularly long standing committees, especially those that have members who have been on the committee for significant periods of time, evoke memories of these in their deliberations. Sometimes this is done with a kind of code known only to local members. A particular name or phrase is used in the discussion of an application to remind members of previous cases, the problems associated with it, and how they were or were not addressed. Decisions related to the earlier case or cases are then used as historical precedent to make a ruling for a new case that may have, or at least appears to have, similar dimensions. In doing this, they deal with the moral panic evoked by the new case and try to prevent problems associated with the precedent from occurring again. This commonly happens if the committee

was somehow held responsible for problems related to the earlier case or cases or knew of other places where the committee was held responsible, such as in the Gelsinger case at the macrolevel or the case of Russel Ogden at the microlevel. The Russel Ogden case involves the issue of absolute confidentiality for participants where Ogden's decision to not reveal the identities of people involved was subjected to legal challenge without the support of the ethics committees and institutions that initially approved the research (Lowman & Palys, 2000). This occurred, in part, because the case occurred during a period of moral panic in the community in relation to euthanasia, the subject of Ogden's research.

Again, what is important about these cases at the microlevel is that they often result in new standing rules, procedures, or expectations at the local level that affect the review of applications. For example, as a result of the Ogden case, the university and the ethics committee put in place new questions on the ethics review form and established a new policy in relation to consent that only allowed limited or provisional confidentiality, a policy that is reported to have had a significant impact on research conducted (or not conducted) at the institution (Lowman & Palys, 2000). A process some refer to as mission or ethics creep, where committees slowly expand their area of responsibility beyond ethics review (Bruner, 2004; Fitzgerald, 2004; Gunsalus, 2003; Haggerty, 2004), can also occur. One result is that later researchers are subjected to greater restrictions based on the possibility of an often-hypothetical result. When multisite research is involved, these local rules or expectations can become a problem with each committee having different expectations and requirements. Many of these can conflict with those of other committees leaving the researcher in a quandary about how to deal with the varying, often conflicting, requirements and expectations. Literature on problems of multisite research associated with multiple reviews makes up a large and growing body of literature on the ethics review process in all the countries involved in this research. Places like New Zealand and the UK tried to address these issues with a regional committee system of review, and recently moved to a centralized system.

CRITICAL CASES AND PUNCTUATED EQUILIBRIUM: MICROLEVEL

As noted in the section above, critical cases can evoke a revolutionary change in local committee activities. Not only can they result in new rules or expectations, they often result in particular kinds of research (by topic or methodology) or the applications by particular researchers (the committee's folk devils) being subjected to higher levels of scrutiny and,

in rare cases, less rigorous scrutiny. An example of the latter might be a decision that as long as particular kinds of research meets particular criteria they can be treated using an expedited review process. Researchers who have acquired the committee's trust by reputation or because in the past they have 'played' the committee's game within its rules well (and those associated with these researchers, like their students) may be allowed some latitude with a later application that might have some 'rough spots.'

MORAL PANIC AND PUNCTUATED EQUILIBRIUM: MICROLEVEL

Other factors, including forms of moral panic and those that evoke moral panic that are not necessarily case specific, can influence meeting patterns. In fact, some of the factors and their effect on the level of activity at particular points in a meeting are relatively predictable.

Here I would like to turn attention to the actual committee meetings, because various forms of moral panic at the local or microlevel seem to evoke a punctuated equilibrium in the meeting process. Here I draw on the work of people like Gersick (1988) and Romanelli and Tushman (1994).

This idea is based primarily on observations of 28 committees in the process of deliberation and formal and informal interviews with some members of these committees. These committees had varying amounts of work to accomplish in a single meeting. Exact numbers of applications are not available for all meetings observed. Based on the available data, the workload ranged from three or four applications for full review to more than 200 applications addressed with 30–40 for first-time full review. Some reports indicated that at particular periods during the year these committees may review 70 or more applications at a single meeting. Similar numbers are reported in accounts in the literature (e.g., National Research Council, 2003). There are committee members who joke that they measure their workload in terms of inches or centimeters of paper. Some meetings were specifically time limited (generally 1 1/2 h); others went until the work was done. The "work until we are done" meetings varied in length, but could last from 5 to 7 h. According to committee member informants, the length of the meetings observed were generally similar in length to other meetings of that committee, although in a couple of cases I was told that the meeting was shorter than usual either because they had fewer applications than usual or because there had been a recent change in procedure. For example, one committee had just instituted an expedited review process and this meeting was described as

being significantly shorter than meetings in the past (1 1/2 h compared to 3 to 5 h). In relation to one particularly long meeting I was told that in the past this meeting was often held over two days so that I had experienced what would have been considered a relatively short meeting (7 h).

With the exception of the couple of meetings where only a few applications were to be reviewed, most meetings had a similar trajectory. Given the number of applications to be reviewed, it is clear that if the time was divided equally across all the applications there would be only a few minutes available for the discussion of each application.³ In fact, each application does not required nor is each given the same amount of time. Obviously there are many factors that contribute to the length of time devoted to each application and there are variations in the pattern. Nevertheless, the pattern I describe here is common enough that after several observations my assistants and I could often predict when there would be a significant change in the pace of the meeting.

When the group moved from the opening 'social' time to the meeting proper the meetings almost always followed a standard protocol for meetings: attendance and apologies, review and acceptance of the minutes of the previous meeting, etc. The primary variation on this pattern was that a couple of committees discussed 'other business' before rather than after the review of the applications.

In relation to the ethics review process itself, there are regular and predicable periods of heightened activity during a meeting and periods where members are more likely to engage in slow and deliberate scrutiny and debate in relation to the applications being reviewed. These periods are not generally related to the actual applications, although a particularly interesting or problematic case, at least in the minds of some committee members, can create periods of static in the process and, on rare occasions form a transition point in the level of activity or speed of review. In between the periods of heightened scrutiny there are short bursts of accelerated activity where applications are reviewed with great swiftness, often only a few minutes per application.

These periods of accelerated activity often begin after a lengthy discussion of one, two, or three applications, particularly when the discussion has branched off on to tangents stimulated by the discussion by not necessarily directly related to the application being considered. The changes are stimulated by behavioral or verbal cues from one or more committee members, one of whom may be the Chair of the committee. These cues including things like people flipping through or arranging the large pile of papers (applications) in front of them and

looking at the clock or a wristwatch to indicate how much work there is left to be done within the time period. A person might comment about the workload relative to the time, indicating the need to make 'greater progress' or 'move faster.'

Behavioral and verbal cues also served to end the period of accelerated activity. In some cases the verbal cues often relate to how fast the committee is working, which serves not so much as a congratulatory comment as to indicate that maybe the committee is moving too fast and, perhaps, not really doing its job. Such comments often indicated a moment of moral panic. One method used to address the moral panic and still respond to the time pressure is to identify issues to be addressed by the researcher without detailed scrutiny of the issues and stating that these can be dealt with 'out of session' by an identified committee member, the chair or the ethics officer.

Other cues that indicate the need for a change of pace include restlessness on the part of committee members or a heightened amount of joking behavior. In a few cases the joke or sarcastic comment suggested moral panic, but just as often these behaviors indicate that the committee needs a break. An example of the first situation occurred after the review of several applications where the researchers suggested they possessed the necessary skills to handle any problem during the interview, one member laughed and commented: "Oh yeah, another one of these: 'Trust me I'm a researcher.'" Often these comments are just indicators that members are beginning to fatigue. However, before a break occurs the committee sort of earns the break by reviewing one or two more applications and they do so with heightened scrutiny. This might be cued by the Chair indicating that it is about time for a break or lunch and setting a quota of applications to be reviewed before the committee receives its reward: "Let's do one more and then take a break. This should be a quick one."

Of course this is often not a 'quick one,' because this whole scene reminds committee members of why they are there. Again, a kind of moral panic sets in, a fear that committee members are perhaps not doing their job with sufficient rigor. Thus, they renew their rigor and apply a higher level of scrutiny to the one or two applications they have agreed to review before the break. After the break the committee members are reinvigorated and for a few applications they again review them with particular scrutiny. Then after one or two discussions, there will again be behavioral cues that there is much work to be done but little time and the process speeds up again.

Thus the periods of greatest scrutiny and discussion occur at the very beginning, shortly before the end of the session and just before and after a break. The last one or two applications often do not involve a high level of scrutiny as members are already preparing to leave the session and their thoughts have already begun to move out of the meeting (e.g., they are packing up, nibbling on the remnants of food or snacks, putting plates and cups away, looking at appointment books, checking mobile phones for messages, and joking or talking with the person next to them). These applications are either approved quickly or a few points are raised with the directive to have them sent to the applicant and the application will be reviewed again either 'out of session' or at the next meeting.

Most committees review the applications in the order in which the ethics officer, who gives the application an identification number, receives them. On occasion an application may be reviewed 'out of order.' The reasons include such things as the researcher who has been invited to attend the meeting has either arrived early or later than anticipated, the most relevant reviewer has to either leave early or arrives later than expected, and, in one case, one application was held until the end of the meeting because the applicant had asked that we, the observers, not be present for the discussion.⁴ Applications that one or more members had identified as requiring some in-depth discussion could also be moved to the beginning or towards the end of the meeting; thus, consciously or not, they placed the discussion of the application at times where in-depth review commonly occurred.

The breaks often occur at regular and somewhat predictable times that coincide with the normal breaks of any work session or workday in these communities. For long meetings these are: morning tea or coffee, lunch, afternoon tea or coffee. Shorter meetings might be punctuated by a tea or coffee break. On rare occasions in relation to a shorter meeting there might be comment about the need for a break but members will say they want to continue so they can finish earlier and have tea or lunch after the meeting. This discussion about whether or not to have a break actually constitutes a break and often affects the level of scrutiny of the next application.

This pattern of committee work is not unusual. Anyone who has sat on a committee can recognize the pattern. There is also a body of research that supports this kind of pattern (e.g., Gersick, 1988; Romanelli & Tushman, 1994). What we see in the pattern of activity of ethics review committee meetings is culturally consistent with similar kinds of phenomena. The one difference may be that the shifts in the pattern, the punctuations, are evoked by a kind of moral panic related to the purpose

of the review: a moral panic about not carrying out their moral duty as members of the committee.

One other kind of situation can evoke a change of pace and heightened scrutiny of applications, often applications that might otherwise get through the process with little comment. This occurs with the one or two applications that follow one that has presented the committee with a difficult situation, particularly one where they have decided to institute a new 'rule.' For example, in several cases when I asked people why a researcher was asked to engage in a practice never before and not normally required, I was told that the review of that application had occurred right after one that had raised particular concerns for some committee members. The committee made a decision about the difficult case and then simply applied the 'rule' to the next case in the name of consistency, rather than considering the fact that the cases might only be superficially similar.

If the committee goes through the applications in some preordained order, like the order in which they were received by the committee, there is no consistent pattern to when the special review cases will occur, but rather than being punctuations, they can often be seen as static in the evolution of the meeting. On the other hand, as already noted, applications that have been identified as potentially problematic may be reviewed out of order at a point where it would normally be subjected to particular scrutiny.

Thus meetings are punctuated by periods of moral crisis (a particular case or the committee is moving too fast to carry out their perceived moral obligation in the reviews) that evoke a slow down in the process of review and then a crisis related to time and workload function to speed up the process again. As in the other studies that have used the punctuated equilibrium analogy or model, in the end the committee generally meets its obligations within its specified time frame if one has been specified. In a couple of cases where the work could not be completed in the allotted time, members talked about setting time for another meeting to complete the work, but for all the observations this option was rejected and either some members agreed to stay until the reviews were completed or the Chair was assigned responsibility for the final applications using written comments from reviewers and the option to contact other members if necessary.

The punctuated equilibrium model as described by Romanelli and Tushman (1994) and the moral panic model described by Cohen (1980) suggest that people and changes in power relations can function as triggers towards a crisis or a punctuation. This holds for ethics com-

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mittees as well. Some people are more likely to evoke change than others, but space does not allow a full explication of how particular individuals use a 'moral crisis' to influence the review of applications or how changes in membership, particularly a change in relation to the Chair, can evoke major change. Here it is probably sufficient to say that many researchers know when there has been a change in the committee; they can tell by the letters they receive and the questions they are asked to address.

CONCLUSION

Punctuated equilibrium/moral panic at the macro and microlevel and the resultant changes in attention to and the criteria for or pace of review have implications for the quality of the review of applications. I have jokingly said to colleagues that I can tell them when in the process they want to have their applications reviewed if they want to get through with little difficulty. Initially this was intended to be a joke, but then I realized that what I was saying had some validity. This does not mean that a poorly presented application or one that presents a particularly interesting ethical dilemma will get through the process easily. What it does mean is that applications that normally would not be subjected to in-depth scrutiny may be less likely to get through the process without questions to the applicant if it is reviewed at particular points in the review process or it is juxtaposed against a critical case that evoked a kind of moral panic among committee members at that meeting or some time in the past. Thus it is not always the quality of the application or the issues it raises that are necessarily the most critical to the nature of or experience with the ethics review process.

The ethics review process is complex and many factors affect the quality and nature of the review: moral panic is just one aspect, albeit an important one. To understand the nature of the moral panics involved and their effect on the ethics review process and the reviews themselves, the review process needs to be considered in context. The moral issues that affect review are influenced by the larger social, political, economic and cultural context in which the reviews take place (Weisz, 1990). They reflect the cultural values and concerns of society at a particular point in time and are enacted in ways that are consistent with social and cultural processes relevant for that context. Weisz (1990) has stated that ethics, as a concept and in the application, are extraordinarily complex. The issues of greatest influence today are not those of 40 years ago. We live in a world with new kinds of moral dilemmas affected only in part by

rapid changes in technology, including communication technology, that result in new forms of moral panic, even if they are not resolved in ways dramatically different from the way moral panics have been dealt with in the past. Understanding the moral panics of today can help us understand the ethics review process better and, perhaps, better predict the ‘turns’ it might take in the future. At the very least, understanding the moral panics that affect the review process might help researchers develop applications that better address committee members’ concerns, or, at the very least, help them deal better with the responses they get from ethics committees.

An understanding of the rhythms of the ethics review process and the factors that affect it at both the macro and microlevel can be used to deal with issues related to the process that addresses concerns of both researchers and committee members. With few exceptions, the people involved are truly concerned about the ethical conduct of research, the enhancement of knowledge that can affect the human condition, and protection of the people involved from risks greater than those of everyday life. Despite these shared concerns, the review process does not always adequately address them. Based on interviews and observations, it is clear that some people recognize the impact of macrolevel moral panics on the review process, even if not so labeled. However, few seem to recognize fully the impact moral panics can have at the microlevel, particularly with untrained, but well meaning, committee members. They may not recognize the impact of microlevel moral panics on the ethics review and decision-making process – and the lived experience of researchers going through the review process. Long meetings with far too many applications covering a range of topics by a group of people with good but limited expertise cannot address the concerns. There needs to be greater awareness of the contextual issues that evoke the concerns of committee members and researchers alike and the impact these have on the kind and quality of research being undertaken. We need to learn from situations that have evoked moral panic, but not overreact to them. There needs to be greater understanding of group processes that affect decision-making, particularly by the Chairs of committees and other leaders in the group – and policy makers. The countries included in this research are all in the process of reviewing the reviewing process. More empirical data is needed to be sure the issues are properly identified and addressed if we are to achieve the shared aim of high quality, ethically responsible research that addresses contemporary needs and populations in appropriate ways. We need to understand the process so it not only better identifies the ethical issues, but deals with them appropriately in a case-by-case basis.

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In this paper, I think I have to some degree addressed van den Hoonaard's (2001) somewhat rhetorical question: Is research-ethics review a moral panic? It is certainly influenced by moral panics and these panics periodically punctuate the evolution of the ethics review process at both the macro and microlevel – sometimes for the better, sometimes not.

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NOTES

¹ As I did not have access to any of the applications, I based this on statements made by committee members.

² In this case the provision of my fieldnotes had not been a previously agreed upon provision in the agreement to allow me to observe, as it was in one other case. The provision of my notes was expressed as a request at the beginning of the meeting when I was introduced to the committee. Under the circumstances, having travelled a considerable distance at great expense to attend the meeting, I did not feel I really had the option of saying no. I was concerned that if I said no then I would be asked to leave the meeting. Thus, in effect, I was coerced into sharing notes that I might have supplied as a courtesy, even though, as proposed by the American Anthropological Association (2003), I did not have an ethical obligation to provide.

³ The times reported in the National Research Council (2003) report from the US for attention to an initial application review at a committee meeting (3–21 min) are consistent with my observations. This is only the time devoted to an application during a meeting. Applications are reviewed by one to all members prior to the meeting and, in some cases, the reviewers produce written comments, which may be reviewed in varying levels of detail during the meeting

⁴ This was one of the few committees that contacted all the researchers with applications to be reviewed at the meeting to obtain their permission for our observation. No researchers attended this meeting to talk about their applications. Committee meetings where a researcher was scheduled to attend the meeting or requested the opportunity to do so were asked before hand if we could observe. This was the only applicant who requested we not be present. The committee decided before we arrived that they would discuss it at the end of the meeting so there would be less interruption to the process that would result if we were asked to leave during the meeting.

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