ETHICS & BEHAVIOR, *16*(4), 377–395

The Research Ethics Review Process and Ethics Review Narratives

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There is a growing body of literature on the research ethics review process, a process that can have important effects on the nature of research in contemporary times. Yet, many people know little about what the actual process entails once an application has been submitted for review. This lack of knowledge can affect researchers and committee members' responses to the review process. Based on ethnographic research on the ethics review process in 5 countries (Australia, Canada, New Zealand, the United States, and the United Kingdom) this article takes the reader through common aspects of the research ethics review process, including some of the kinds of narratives that influence decision making. Greater understanding of the nature of the review process and the narratives that often form the core of the process can help contextualize responses that researchers get from committees so they can better address them. It may also help committee members reflect on how these narratives influence their decision making and the responses they make to researchers.

Keywords: research ethics review, research ethics committees, ethics review narratives

There is a growing body of literature on the research ethics review process, a process that can and does have important effects on the nature of research in contemporary times (Fitzgerald, 2005a). This literature generally highlights structural and process issues and problems in the ethics review system. However, something that is missing in this literature is what actually occurs within ethics committee meetings. For most researchers, the ethics review process, in particular what happens during ethics committee meetings, is like the proverbial black box (De Vries & Forsberg, 2002; Fitzgerald & Yule, 2003). Researchers put an application in one

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side of the box and out the other side comes the "please explain" letter, an often decontextualized request or demand for additional information or changes in some aspect of the research.

But what exactly happens in the review process and these committee meetings? This article describes the process as revealed through an ethnographic project on the ethics review process as culture and cultural process. It makes transparent aspects of a process that is, in many cases, shrouded in secrecy and conducted behind closed doors. It is an attempt to take a peek behind closed doors (Ashcroft & Pfeffer, 2001; Fitzgerald, 2004; Lo, 1991) at the ethics review process and committee meetings to explore what some have called secret ethics committee business (Fitzgerald & Yule, 2004; Gillam, 2003). In doing so, we highlight one particular feature of committee meetings, something we call *ethics review narratives*.

METHOD

This article is based on ethnographic data collected from 2001 to 2005 as part of a study of the ethics review process. It is based on observations of 29 ethics committee meetings in five countries (13 in Australia, 2 in Canada, 3 in New Zealand, 4 in the United Kingdom, and 7 in the United States) in the process of deliberation and formal and informal open ethnographic interviews/discussions with key informants (i.e., ethics committee members, chairs, ethics officers, policymakers, researchers) involved in the review process. The interviews/discussions were based on the ethnographic interview style, as described by Spradley (1979). Formal interviews/discussions involved 213 people (79 in Australia, 52 in Canada, 16 in New Zealand, 15 in the United Kingdom, and 51 in the United States) from a total of 37 cities or metropolitan areas. Many of these people have experience with more than one relevant role, and many committee members have been or are members of more than one committee. Thus, the number of committees for which we have information is far more than the 29 observed. The work is also based on analyses of ethics review related documents, policies, Web sites, and literature.

The meetings observed, and those for which we have information, cover a range of committees—regional, local, specialist, and institution-based—with most dealing primarily with medical research and a few oriented primarily toward social and behavioral research. Of the committee meetings actually observed, 18 were associated with a hospital, area health service, or other local or regional primarily medical research entity; 8 were university based; the rest represent specialist committees. Only 3 identified themselves as primarily oriented toward social and behavioral science research. Many deal with applications covering a variety of topics and methodologies. One committee was observed on two occasions, and some committees were different committees within a particular institutional authority. The observed meetings lasted roughly 1½ to 7 hr. The first author observed all but two meetings and conducted nearly all of the formal interviews, some with one of the other two authors present. Two meetings were observed independently by another author. The first author and another author simultaneously observed nine meetings.

Despite the fact that the ethics review process in each of the countries involved is based on different sets of regulations or guidelines and laws, our observations suggest that the actual meetings and the narratives within them are similar enough in this case to deal with our body of data as one body of data. Thus, although there are differences across countries and committees, we focus here on a remarkable commonality, the narratives involved. When asked by some committee members after the meetings how they compared to other committees, we often joked that if we could modify the accents of the people involved and a few of the acronyms and terms, people probably could not tell in which country the meeting occurred.

THE PREMEETING PROCESS

Before discussing the meetings themselves and the narratives they involve, we set the scene by reviewing what happens before the actual meeting. In doing so, we acknowledge that the review process is complex and many staged, and what happens in meetings makes more sense when set within this more extensive context. We also present this information because, although some committees include information on this aspect of the process on their Web sites or in other documentation, most researchers, and some committee members, are unaware of this process or only know aspects of it.

We present the general case here, but, like all processes, there are variants. For example, in some places there may be a review at the local department or administrative unit before the applications go to the ethics committee, and in some cases all expedited reviews take place at this level. Here we begin at the point where the ethics office receives the application.

Once an application is submitted, an ethics officer reviews it.[1] This person reviews the application to be sure it is submitted on the appropriate form, has all the right boxes ticked, has all the necessary signatures, and includes any necessary accompanying materials. This person logs the application into the system, identifying any key features, such as the type of research (clinical trial, qualitative, etc.) and perhaps the area of practice, such as the area of medical specialty or discipline, and gives it an identification code. At this point, the work is purely administrative.

[1] *Ethics officer* is used as a generic term for the administrative person who supports the work of the research ethics committee. Many institutions have a single person in this role, but large organizations may have several, include one designated as the director or some other formal title.

In some institutions this person may also do the first review of the application to highlight issues that may need to be addressed and at this point may, in fact, send the application back to the researcher for revision based solely on issues identified at this level. A copy of this review may be submitted to the chair and/or the primary reviewers. What happens next depends on whether it is an open or closed committee (Fitzgerald & Yule, 2004). In open committees, the ethics officer or the chair might contact the researcher if there are areas that they are sure the committee will want addressed so the researcher can address them before the application moves along in the process. In closed committees, generally there will be little or no contact with the researcher by anyone associated with the committee. The researcher will be asked to respond to the issues, but only after the full review has been completed and the researcher has been sent a formal letter.

At this stage, the ethics officer may take on varying levels of responsibility in relation to the potential ethical issues presented by the application. The amount of responsibility afforded the ethics officer varies considerably from one institution to another. It is becoming more common for institutions to hire people with professional credentials in these positions and give them greater levels of responsibility. How much responsibility the ethics officer has in regard to the review generally depends on the relationship, past and present, with the chairs of the committee, and the individual's level of experience and personal attributes (both positive and negative)—and whether these are acknowledged by the chair and the institution.

Once the initial review of the application, which focuses primarily on the form itself, is completed, the application is then commonly assigned to reviewers. Information like the type of research and the domain in which it falls is used to decide to whom the application will be assigned—and whether it will be entered into the expedited or full committee review process for those committees that use a form of expedited review. The assignment is often done by the ethics officer, but in some cases it is done by the chair or the ethics officer and the chair, depending on the level of responsibility given to the ethics officer and whether the application presents any particular concerns in relation to the research proposed or the availability of an appropriate reviewer. When in doubt, ethics officers, even those with high levels of responsibility, generally confer with the chair before making an assignment.

Expedited review is understood in two ways: a fast-tracked application (the process is the same for all applications, it is just put through the system more quickly), and a review process that is different in character from a full committee review. In the latter case, the review might occur at the department or subcommittee level, with the decision noted at the committee or ethics office level without further review. Expedited review is often assumed to be associated with a quicker turn around time, but this is not always the case. The second type is consistent with how expedited review is defined in U.S. regulations. When applications for expedited review are conducted through the ethics officer, they are generally sent to the reviewer or reviewers as soon as the ethics officer has processed the application. In some places, only the chair reviews applications for expedited review, using other committee members as necessary to deal with issues where the chair feels he or she needs some assistance. In other places, the application will be assigned to a subcommittee, but more often it is assigned to at least two members of the committee to review outside the full committee meeting. One reviewer is generally a person recognized as having some expertise in the specialty area associated with the application. The second reviewer is often a person with little or no expertise in the area, to obtain what might be called the naïve review. In some places, one of the reviewers is always a lay member. The same criteria are generally used in assigning reviewers for applications that will undergo full committee review. Occasionally there is no one on the committee with the relevant expertise. A few committees use the option available under most national guidelines and use an outside reviewer for such applications, but most committees do not often use this option.

Once logged into the system, applications earmarked for full committee review may go directly to the primary reviewer and, if relevant, secondary reviewer, but generally all applications are held by the ethics officer until a few days to two weeks before the committee meeting. Then all the applications are sent out to the members as a packet, often a very large packet. (One of the permutations of this is that all committee members receive a portion of the application, such as the core application and the information sheet and consent form, with only the primary and secondary reviewers receiving the full application.) During this period, the chair, who generally functions as a primary reviewer, may begin his or her review of applications.

Thus, all ethics applications receive an in-depth review by at least one person, most are closely reviewed by two or three people, and in some cases all members of the committee are expected to conduct a thorough review. The membership of the committees can range from 7 to 30 people.[2] The observed meetings generally had 8 to 15 members at the meeting, although the number sometimes varied throughout the meeting as people came and left. Large committees almost always use the primary/secondary reviewer structure. On rare occasions, the chair acted as the sole primary reviewer. This answers a common question by researchers: "Does anyone actually read the application?"

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[2]Each country requires or recommends that the committee be made up of a minimum number of people and that the membership include people with particular kinds of expertise. There are minor differences in these recommendations across countries, but they are fairly consistent in terms of the basic membership, that is, lay and professionals as equally divided as possible between men and women. Some committees have included additional requirements (e.g., a statistician).

THE MEETING

The process described here relates to face-to-face meetings based on our observations and interview data. Some institutions conduct most reviews using an e-meeting process and meet face-to-face only to deal with applications that they feel require an interactive discussion.

Once meetings got under way, they followed a trajectory similar to that of other formal meetings: attendance and apologies,[3] review of the minutes, matters arising from the minutes, and so forth. Other business, like reports on activities undertaken by members since the last meeting—such as attendance at some related meeting, or announcements about training opportunities or relevant literature—took place either before or after the review of applications. Some committees reviewed matters pending from the last meeting, like responses from researchers, before reviewing new applications; others did these after the new reviews. For the most part, the core of the meeting focused on the review of new applications, but in some cases considerable time was devoted to applications that had been returned to the committee for further review following a response from the researcher or that had already been reviewed by another committee.

For most committees there was an expectation that all members would have read all the applications (or all the material provided to them) before the meeting. Some committees did not assign primary reviewers, but most of those observed and discussed in interviews did. The primary reviewer is expected to have conducted an in-depth review of the application and all accompanying materials. Many committees have produced a form to guide the reviewer. Reviewers may or may not have filled out the review guide. This varied by committee and by member. The secondary reviewer was also expected to have conducted an in-depth review of the application and all accompanying materials, but in many committees this person (often a lay member) was primarily responsible for reviewing the information sheet and consent form. Some committees have a third named reviewer, in many cases this person was the statistical expert, although, particularly for clinical trials, this person could be an expert in pharmacology or physiology.

If one of these reviewers was not able to physically attend the meeting, there was an expectation that the member would submit a written review (which may or may not have been in a narrative format) with a recommendation about whether or not to approve the application and, if relevant, under what conditions. Other members who could not attend might also submit written reviews, notes of concern, or

[3]This expression is common in all of the countries except the United States and refers to a listing and acknowledgment of the people who are at the meeting and those who have indicated that they will not be attending the meeting. This is done for at least two reasons: first, so the information can be included in the record of the meeting and, second, it is used for determining whether or not there is a quorum for the meeting.

specific questions, with or without a recommendation about whether to approve the application.

There was one rare exception to this format. In this case, the primary reviewer provided a summary review in writing to the ethics officer, who then distributed the summary to other members. In such cases, the members may not receive the full application but may request a copy before the meeting or may view the copy available at the meeting. The Chair would have received and reviewed the full application. In this case, basically the only information the other committee members had upon which to make their decision was the written and verbal ethics narrative by the primary reviewer and, if relevant, the secondary reviewer or Chair's comments and responses to members' questions. This is similar to the process described for one institution in Canada for which it has received formal criticism (Payne, 2004).

THE IN-MEETING REVIEW PROCESS

The *ethics* or *core* narrative was a common component for most, but not all, committee meetings. This narrative was the reviewer's account about the project that provided the stimulus and focus for the committee discussion that would follow. It shaped the nature of that discourse both by what was offered in the narrative and what may have been left out. Ultimately it seemed to affect the final decision by directing the members' thoughts and discussion in a particular direction, especially when someone accepted as having authoritative knowledge offered it. The skilled raconteur and the skilled debater, whether or not the person has authoritative knowledge, can exert considerable influence on the decision-making process through this and other in-meeting narratives. People with strong personalities or in particularly powerful positions can also be very influential. As some informants noted, lawyers on committees can often be particularly influential because of their occupation-related skills in developing and presenting authoritative arguments and their ability to engage in debate. Others who can be particularly influential are members representing particular populations. For example, Māori members on committees in New Zealand are often deferred to even if others did not seem to be in total agreement. People without authoritative knowledge, particularly when confronted by a person considered to have such knowledge and who may also be particularly forceful or skilled at presenting a case, often do not challenge such a person even when they have questions or concerns with the person's presentation. On the other hand, there are nonexperts who are particularly skillful in raising questions and concerns that do not challenge others' authority. They often did this by first noting that they did not have expert knowledge and thus need the help of the experts to understand the point, often asking for it to be put into language they could understand. In doing so, they often evoked a new narrative and discussion of the topic because others, who might not have been willing to express their lack of understanding, were now in a position to enter into the discussion or debate.

There are important variants that do not quite fit a strict narrative approach. In one variant, the chair introduced the next application to be reviewed by announcing the application number, possibly the researcher or researchers' names, and the title of the project with, perhaps, a few words that expanded on the title to help orient members as to which application was now before them. This information was presented with no story or editorial comments. The chair then opened the meeting to general discussion. This simple summary statement was used to make a transition from one application to another and generally contained little that was likely to be influential in decision making. However, the initial speaker could often influence the direction of the discussion. This approach was most likely to occur with projects that everyone already knew about because they had been discussed in another context, like an earlier meeting, but it could also be used in meetings where there were no primary reviewers. A second permutation on this was that the chair then went around the table and asked each member for the member's comments. In these versions, all committee members ostensibly acted as primary reviewers. Another variant was that once the project had been introduced, the chair or the primary reviewer took the committee through the application section by section, providing a brief comment or narrative that opened the committee discussion.

In many cases where there were no assigned reviewers, the chair provided the primary narrative as part of the introduction to the application. In the more common case, the chair introduced the application by such things as number, title, and researchers' names, sometimes adding the names of primary and secondary reviewers, and then the chair would hand the meeting over to a primary reviewer. Thus, at this point the members may have already heard a narrative on the project by the chair, but more often the first significant narrative was by a primary reviewer (or if a primary reviewer was absent, then a secondary reviewer). This narrative was a critical part of the review process, even more critical than the applicant's narrative.

THE APPLICANT'S NARRATIVE

Most application forms require applicants to supply a short, plain-language description of the project. Applicants are generally directed to write this summary or abstract in language that would be understandable to the average layperson. This summary has the potential to be a narrative on the project, and in many cases it is, but most forms do not allow sufficient space to make this a truly informative narrative. For example, some forms allow only 100 words, or the block available on the form provides only enough space for a very brief description. Most forms then either ask the applicant to attach the full protocol or proposal or they provide space, often limited to about two pages, for a detailed description of the project, including its purpose and significance, details of the research design or data collection methods, and forms of analysis. Some forms force the applicant to break much of this information into parts with separate spaces for each part of the project description. This longer description is (or can be) the applicant's narrative of the project. The purpose of keeping this information short and concise is, according to our informants, to limit the amount of reading each member must do, particularly when they have many applications to read. The space limits may, in some instances, be self-defeating, as there may not be enough space for the applicant to provide all the information that the members need to make an informed decision. One result is that the application goes back to the researcher for more information that might have been included in the original application if there had been enough space.

For those meetings where researchers normally attend the meeting or may be asked to attend, the researchers were often offered the opportunity to present a verbal narrative of their project, but this generally happened after the members had already heard and discussed the reviewers' narratives. This narrative can influence decision making, but it does so in the context of the reviewers' narratives, narratives the researcher has not heard because they occurred before the applicant entered the room.

THE ETHICS OR CORE NARRATIVE

The primary narrative in the meetings was not the researchers' written (or verbal) narrative, even in situations where the application form provided space for a succinct project narrative. All the members may have read this material (although occasionally committee members admitted that they had not read a particular application). So this narrative should be part of the information that members bring to their decision making, but, in the meetings that we observed, we saw the most influential narrative being the one presented verbally by reviewers at the meeting, particularly the first reviewer to speak. This primary or core narrative served two purposes. It identified and introduced the application to be discussed and set the stage for the discussion. At least initially, the discussion that followed was a response to the narrative. There are three primary types of narratives: the factual, the analytical, and the opinion.

Factual Narratives

The factual narrative, the least common form, was a brief summary of the project without clearly identifiable editorial or analytical comment. It served to remind those who had read the application what it was about, and informed those who might not have actually read the application or might not have read it closely. In a version of the factual narrative, the reviewer added comments after the narrative, often ending with a comment about whether the person thought the application should be approved, approved with particular changes, or returned to the applicant for significant revision. Rarely did primary reviewers suggest outright rejection at the end of any form of narrative, although the narrative or additional comments could make it clear that this was what the person would have liked to suggest.

Analytical Narratives

The second form of narrative was an analytical report that highlighted issues and concerns and particular strengths, if any, or weaknesses throughout the narrative ("I liked the way they presented …"). It presented an analysis of the application, highlighting points of particular interest or focus for this committee. Some of these points are common to most committees, like the quality of the information sheet and consent form.

In this form of narrative, the reviewer's opinion was generally quite apparent within the first few sentences. "This is a nice little project that …," "I have no idea what this project is about, but it seems to be …," "I have some real problems with this application …," "This is a really well-written application …," "I liked this application …," "I really enjoyed reading this application" (this could be presented as either a very sincere statement or as a sarcastic comment), or "This is good bedtime reading. It will put you right to sleep." However, the reviewer's opinion was even more explicit in the opinion narrative.

Opinion Narratives

In opinion narratives, the reviewer's position was explicit and often focused. "This is trivial research that will just waste people's time. It is unethical to waste people's time." "This application is so bad I do not know why we are even considering it. It needs to go back to the researcher for major revision." "This project cannot possibly come up with the result they suggest given the [e.g., research design, sample size]. It would be unethical to approve this project." In some cases, the reviewer simply presented the application as not worthy of any real discussion because it was so bad, but more often the narrative focused on particular areas to highlight why the opinion was justified. Opinion narratives were not always negative, but the negative was far more common.

THE IMPACT OF THE NARRATIVES

The reviewer's narrative was the reviewer's version of the applicant's story about the project, and it may or may not be an accurate reflection of the project, because the narrator chooses what to present in the narrative, whether or not there is a reviewer guide. As observers, it was the only narrative we had about the project, so we could not determine whether or not it was an accurate representation of the application.[4] The only hints we had on its accuracy were based on comments others might have made in response to the narrative or points that came out in the discussion. In this way, we were like committee members who might not have read the application or who might not have read it closely. Considering the number of applications reviewed at some meetings (up to 70 a meeting), it is highly unlikely that even the most conscientious members could read all applications closely or remember the details of each application. For complex and very technical applications that might have been beyond the comprehension of some committee members, this narrative might have been, and in some cases clearly was, their first real introduction to the application. "Oh, so that is what it is about."[5] "Oh, now I understand. I didn't get that part about … ."

What was apparent to us was that this narrative often had an influence not only on the discussion that followed, but it often influenced the final decision, particularly if the narrative was positive in tone. Negative narratives generally evoked considerable, often heated, discussion, even when people agreed with the opinion of the narrator. If the primary and secondary reviewer were in accord, then the application was generally returned to the applicant with a list of questions, or the committee would decide to have the applicant attend the next meeting. If these two reviewers did not agree, then the one with the more powerful argument, the one identified as having the greatest expertise in the area, or the one who could stimulate significant others to raise objections generally, but not always, won out.

There are two particularly important points about this narrative and its impact on the review process and the discussion that occurs within meetings. First, it is essentially a presentation of the reviewer's textual analysis of the application in narrative form. It is a verbal presentation of that person's understanding of the application and the person's assessment of the research. If the narrator understood it, no matter how well or badly the application was written, this influenced the nature of the narrative as much as if he or she did not understand it. If the reviewer did not understand it, for whatever reason, including the person's lack of knowledge of the topic or methodology, then this often raised questions for members that they might not have had before they heard the narrative or began to discuss it. Even when lis-

[4]In only one case did we have the applications before the meeting. This committee felt we could not understand their deliberations without having read the applications. The applications were provided with the consent of the applicants. In most cases, we had access to copies of the applications, but only after we arrived for the meeting. So we had little time to look at them, given that our attention was on the process, not the applications. In a few cases, we did not have direct access to copies of the applications.

[5]Although all the authors have health-related backgrounds, we often had difficulty understanding the language in some applications and narratives. We assume that this would also be the case for some committee members. On the other hand, there was language relevant to qualitative research that we understood, but it was quite obvious that others did not.

teners understood (or thought they did), the narrative could lead people to question their initial judgment. They might indicate that they must have missed something important, not that their new questions or doubts might have been a product of the narrative or one person's assessment. Sometimes this was voiced in statements like: "Oh, I thought it was about …," "I thought that what they proposed was …," or "I understood that they …." The members might then enter into a debate about what the project was about or some aspect of the proposal, and members could be swayed one way or another. Some argue that this is the strength of the committee review process; no single person is likely to pick up all the potential issues. If this is, in fact, different people picking up on different issues, this is probably a good thing, but it can also mean that things that were not issues or that should not be issues become issues and are often then presented as issues to be addressed by the researcher.

Second, the narrative provides the starting point and initial stimulus for the discussion. It can serve to establish the direction in which the discussion will move, and often focuses on areas that are particular issues for that committee. At least initially, people respond to the narrative—not the application. They might refer to the application to support their comments, but they are generally responding directly to the narrative. One result is that sometimes the discussion gets off on tangents generated by the narrative, and sometimes people lose sight of how this does or does not relate to the actual application. Thus, at some point, as a result of this discussion, the committee came to think that an applicant had not addressed an issue when the applicant actually had, or that the applicant had said something he or she had not. In one meeting, a member said that the applicant had not addressed a point in the information sheet and that the applicant needed to do so before the person would approve the information sheet. Just as the person finished saying this, with the ethics officer writing it down, another member said, "But they did say that. It is right here on page x of y." The committee had lost sight of what it was doing, not only because of a long and complicated information sheet (in this case an eight-page form), but because the discussion itself took the committee off on a tangent where they lost sight of what the applicant had actually provided. A common comment from researchers who have received letters that might fall into this category is, "Did anyone actually read the application?" If this committee member had not picked this up during the meeting and the ethics officer or chair had not checked it before the letter to the applicant was sent out, the applicant could reasonably wonder if anyone had read the application or information sheet.

Often the chair would intervene if there was considerable difference of opinion and suggest some middle-ground approach like asking the applicant to respond to the questions or asking the applicant to attend the meeting. In fact, one way for chairs to end a discussion that was either not going to be resolved through discussion or was taking up too much of the meeting time was to suggest, "Let's ask the researcher." We do not know whether or not these questions were actually sent to the researchers, as we have never seen the letters sent out in relation to any observed reviews. But, having observed this process, some questions we have seen on letters make a new kind of sense; the researcher got the question because the committee could not, or would not, resolve the issue during the meeting, or the discussion got away from the actual application and this was one way for the chair or members of the committee to get the committee to move on, or it was a result of the nature of the reviewer's narrative.

We know from interviews with ethics officers and committee chairs that some of them review the list of items to be sent to the researcher and often do not include every item identified at the meeting in the letter. In some cases, one or both of these people review the application again before the letter is sent out to be sure the issue had not already been addressed in the application, but this fact got lost in the discussion. Given the information available to us, the tone of the letters may not match the tone in which the issue was raised during the meeting. For example, an emotionally charged issue might be offered in more temperate language in the letter. Others seem to simply send out the list as it was constructed during the meeting. What happens here seems to depend primarily on the level of responsibility taken by or given to the ethics officers, but ethics officers, even those who commonly do compare the committee's questions and comments to the application, also point out that this can take a lot of time, time many ethics officers feel they do not have given their workloads, which can be substantial.

In some places, the applicant is always invited to attend the meeting. While the applicant was waiting outside the room, the chair would often try to make a list of the questions the committee might ask the applicant and would help the committee identify who would ask which questions. Generally, the person with the greatest concerns was identified as the person to ask questions related to their specific concerns. The member's comments were often more temperate when the person had to actually talk directly to the applicant. In situations where the applicant does not attend the meeting, some (but not all) committees will appoint a member to talk with the applicant regarding the committee's questions or concerns. This was more likely to happen if there were a number of issues to be addressed or there was something that might be viewed as particularly sensitive and a letter did not seem to be the best way to communicate these to the researcher. One person said that their group often appoints a second person to go with the designated member to be sure this person was "not too hard" on the applicant, but that this was the exception rather than the rule.

The primary result of this process was that few applications were rejected outright. In fact, outright rejections were rare (and this is supported by reports in the literature; e.g., Boyce, 2002; McNeill, 1993). Applicants generally received a list of questions or matters to be addressed, many of which were rather minor (e.g., correction of typographical errors, changes in wording or formatting of information sheets and consent forms). Few applications are approved as submitted. In some places, no applications are approved as submitted. There seems to be some need among committee members to make some comment or request some action. This may be one of the ways that members address the kind of moral panic described by Fitzgerald (2005b). If they do not make some comments, then there is a sense that they are not fulfilling their responsibilities as a committee.

There are other kinds of narratives throughout committee meetings, often embedded in the discussion. Narratives are used to make a point about an application or to suggest that something in particular needs to be done. These narratives may refer to other discussions, both within and outside the committee. One of these kinds of narratives, which might be called a *historical narrative*, begins with "Remember when we … ." Thus, stories of past events are brought into the discussion to make a point someone thought was relevant to the case before them. In some cases, these narratives can be found within the core summary narrative, as part of the story about a specific application.

THE "WHAT IF" NARRATIVE

There is another important kind of narrative embedded in the meetings that influences decision making. This is the *what if* or *worst case scenario* narrative. Such narratives were most often related to discussions about potential risks, but also dealt with such things as design and recruitment issues. They were often generated by the primary core narrative, but also came out of the discussions that followed. This kind of narrative is generative, as each potential version of the story builds on the one before it, and each version becomes more and more serious until it gets to the worst scenario they can come up with, one that may significantly overestimate the kind, potential for, probability of, or seriousness of the risk (see also, e.g., Church, 2002; Haggerty, 2004; Israel, 2004). Such scenarios evoke a moral panic that is addressed in the response to the applicant (Fitzgerald, 2005b; van den Hoonaard, 2001). In some cases, the discussion focused on the likelihood of that scenario, but more often the scenarios seemed to take on lives of their own. They can develop to the point where an uninformed listener might wonder if this research was worth the risk because as the versions of the hypothetical develop they become more and more believable and members with a moral conscience are placed in a position where they feel they have to raise questions about whether or not the project should be approved or approved as presented.

Again, often this situation was resolved by sending the issue back to the researcher to address. Given the low probability of some of these worst case narratives actually happening, it is not surprising that researchers, not having heard the discussion, wonder where such ideas come from. They do not realize that they are a product of the narrative processes that occur within committee meetings, but ones the researchers are not generally privy to. Thus the question to the researcher or the concern raised is decontextualized and, as a result, the researcher may consider such questions strange and even irrelevant to their research. The committee and the researcher are using different bodies of information as the reference point: the committee's is the narrative, the associated discussion, and, perhaps, their understanding of the guidelines or regulations; the researcher's is the submitted application (and any other relevant information they might possess that they did not include or saw no need to include in the application).

PERSONAL EXPERIENCE AS EXPLANATION NARRATIVE

Ethics committee meetings are filled with narratives. Some are just part of the social discourse found in any social group interaction. These narratives establish and reaffirm relationships. There is, however, one more kind of narrative that occurs frequently in meetings that needs to be mentioned. This is the *personal experience* narrative; a narrative based on the committee members' own experiences, particularly in relation to research, or a story of a known other's experience (friends, relatives, research participants). These narratives serve to contextualize, explain, or introduce a matter of some interest or concern in relation to the discussion. The narrative may or may not have direct relevance to the application being discussed, but becomes attached to it because of the context in which it is offered. These narratives are regularly related to the what if narratives to help support the possibility of such situations happening. In some cases they are, or take on the character of, urban myths or contemporary legends (Haviland, 1996). They are told as true; they often cannot be attributed to any known person; there are often multiple versions, but in spite of the variations, they are told in such a way and with enough detail to be plausible; and they tell something about the society in which this committee operates. As Haviland pointed out, such narratives serve to entertain and instruct. They provide clues about "what constitutes approved or model ethical behavior in a culture" (p. 397).

THE IMPORTANCE OF THE NARRATIVES

Much has been written in recent years about the narrative as research method and object (Cortazzi, 2001). Consideration of narratives, naturally occurring and contrived, has long been used to provide insights into various aspects of human life. People communicate through narratives. They are part of everyday life and the substance of everyday talk. They are situationally dependent and socially constructed. Narratives are used to illustrate a point, communicate, even to entertain or communicate in an entertaining or interesting way. They are "constructed to suit occasions and are crafted in such a way as to further the speaker's current agenda" (Burr, 2003, p. 23). They are purposeful. Thus, a core narrative is often structured and restructured to fit the audience and the context, and may have different purposes depending on these variables. Many narratives are moral tales used to teach and inform. "We tell each other and ourselves stories that powerfully shape our possibilities" (Burr, 2003, p. 19). People use them, intentionally and unintentionally, to sway others and put forth particular agendas. People use them to think with, and often create multiple versions of a narrative as a way to consider potential outcomes if some aspect of the story should vary. In other words, people often create *what if* stories as a way to consider possible outcomes.

People also use narrative and the ability to construct a good narrative in identity management and to demonstrate competence. As Good (1995) noted for clinical narratives, doctors and medical students demonstrate their clinical competence, in part, by demonstrating competence in the creation of appropriate, succinct clinical narratives. In these narratives, they use their knowledge of the domain and their audience to develop a narrative that can be used to persuade others of the appropriateness of a treatment or course of action. In doing so, they also demonstrate that they can produce a "'moral' professional voice" (Good, 1995, p. 203). The core ethics narrative might possibly be a product of the fact that, initially, ethics committees were dominated by doctors and originally dealt almost exclusively with medical research (McNeill, 1993)—and many are still dominated by doctors and are primarily medical research oriented.

Whatever the origin of the ethics narrative, it is now a key feature of the ethics review process and it is familiar to many members (doctors, other health professionals, lawyers, etc.). Some of the lawyers who participated in this project noted that they are trained to make convincing arguments; this is a core skill of their profession. Furthermore, when they sit on a committee, their authoritative voice as lawyers, like that of doctors, often goes unquestioned by those who see such knowledge as beyond their area of expertise. Through the narratives (and others' responses to the narrative), narrators, particularly new members and lay members, demonstrate their competence as reviewers and their appropriateness as members of the committee. Based on both observations and comments of members, new members are quickly socialized into constructing appropriate narratives, generally within a couple of meetings. Members use them, in part, as an identity management strategy to demonstrate that they have the appropriate moral voice and knowledge or expertise to be sitting in judgment of these applications. More established and accepted members and experts are assumed to have this moral voice and the expertise to present it, and this adds power to their narratives. Thus, members use the narrative to present a moral case for why they believe any particular part of a project, or the project as a whole, should or should not be supported. Even when the narrative does not deal with ethical issues like autonomy, beneficence (risk/benefit), or justice, the guiding principles of ethics review in these communities, they are still presented as moral narratives. Thus, concerns or differences of opinion about methodological issues and personal values and opinions are couched in moral terms; something we could call a *rhetoric of ethics*. This explains, in part, why methodological issues are so commonly addressed in the committees' discussions and the letters that are sent to researchers.

Because the core narrative is the introduction to the discussion for the application, it has great power to influence the direction and content of the discussion, although other factors are also involved. When a narrative is used, the members respond initially to the content of the narrative, not to the content of the application. The narrative sets the stage for the discussion by concentrating on particular aspects of the project—ones that may or may not be the emphasis of the application—and thus sets particular agendas for discussion. There is an implied assumption that the narrative is actually about the application, rather than the application being the stimulus for the person's narrative. Some narratives sound like brief summaries of the project with little editorial comment, and many are, but others are a dialog on some issues in the application that the reviewer found of interest or concern. And, those that are summaries still end up highlighting some issues over others, even when they are reasonably factual. The result is that some narratives can lead the discussion that follows into areas that may have little to do with the proposed research. In some cases, the whole discussion is on these issues and others are not addressed.

However, when the initial discussion had run its course or was interrupted by the chair or another member of the committee, then there was the opportunity for either the secondary reviewer or another member to raise issues not yet addressed. Whether this happened or not depended on several factors. One of the most important factors was time. If a committee had many applications to review (and committees usually do), then issues some members might have wanted to discuss got tabled and may have found their way to the researcher through written comments from these members that were submitted to the chair and/or the ethics officer to be included in the submission to the researchers. Another factor that could influence whether or not the discussion went on to other topics had to do with the level of intensity of a particular discussion. If there was a high level of emotional content, the chair or another member might have taken action to move the discussion on to another application or less provocative topic. One way that this was done was for the chair to try and summarize the discussion and get the committee to make a commitment to what the researcher would be asked to do.

CONCLUSION

In this presentation on the ethics review process, we have focused on providing a description of some of the basic processes, which may be unfamiliar to some, and the kinds of narratives that are critical to the nature of the review process and the responses researchers get from ethics review committees. It is difficult to convey in a short article the power of these narratives to influence decision making. Our objective here is not to suggest whether or not such narratives should be a part of the process. Narratives are a natural part of verbal discourse and are always going to be a natural part of human gatherings such as ethics committee meetings. Our objective is to inform people that they are a part of the process and that they can, and do, affect the nature of the review process. Understanding that narratives often act as the stimulus for discussion and decision making helps to contextualize the material that is subsequently sent to researchers. Knowing this can help researchers develop an understanding of why they might be asked particular questions. Because of our observations, when we read responses from ethics committees we find that we develop hypothetical narratives that we think might simulate the ones that evoked this comment. This gives us something upon which to develop a response. If our hypothetical or *what if* story is similar to the one in the meeting, then we respond appropriately; if not, we get another letter.

Should the core ethics narrative be a part of the process? We have no answer to this question. Its intention is to help manage a large workload in a timely fashion and provide structure to the review process. For committees that must review large numbers of applications, it may be the only way to deal with the workload. Committees with smaller workloads can potentially manage the review process differently. Thus, although we do not make any recommendation on whether a core ethics narrative should or should not be part of the process, we do recommend that narrators and listeners develop a greater consciousness about these narratives to recognize how the narrative, rather than the application, influences the discussions and decision making that occurs in meetings. Being aware of how influential such narratives can be can help committees sift the wheat from the chaff.

ACKNOWLEDGMENTS

We thank the many people and committees who so generously shared their time, thoughts, and experiences with us, and the key informants who read and commented on drafts of this article. This project was funded in part by a University of Sydney Study Leave Grant and an Australian Research Council Discovery Project Grant (DP0343014).

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