September 1984

Tort Liability of Institutional Review Boards

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STUDENT MATERIAL

Note

TORT LIABILITY OF INSTITUTIONAL REVIEW BOARDS

I. INTRODUCTION

Institutional Review Boards (IRBs) represent an attempt to resolve the conflict that arises when an investigator undertakes research involving human subjects. In his quest for knowledge and perhaps career advancement, an investigator is not a likely candidate to weigh fairly the inherent risks to the human subjects who participate in the project. Investigators justify or rationalize their research practices by extolling the great advances in medicine and science made possible by research involving human subjects. On the other hand, advocates of government regulation of research are quick to point out the serious injuries and deaths inflicted on many human subjects as the result of unscrupulous research methods. They add that many of those injured were never fully informed of the risks inherent in the procedures or given the opportunity to decline participation. IRBs were proposed as entities which could balance all of the interests at stake and arrive at an equitable result.

This Note will address the potential legal liability of individual members of IRBs and examine the steps these members can take to protect themselves against liability.

II. BACKGROUND

During the 1960's, reports of several research projects involving abuses of the rights of human subjects became well publicized and generated great concern. This resulted in a surge of public indignation and a growing constituency advocating increased government regulation of research involving human subjects.\(^1\)

Advocates of increased regulation of human experimentation pointed to not only the Nuremberg prosecution of Nazi physicians who conducted barbaric research in concentration camps,\(^2\) but to almost equally appalling examples of disregard for human subjects in experiments in the United States.

The most frequently cited example is the Tuskegee syphilis experiment\(^3\) conducted by the United States Public Health Service from 1932 until 1972. The

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experiment was designed to study the effects of untreated syphilis, and used as its subjects 400 black men in Macon County, Alabama. Although penicillin was discovered in 1929 and found to be an effective cure for syphilis, treatment was withheld from participants in the study. The atrocity cannot be attributed to the recklessness of a few mad scientists. The forty year study involved doctors in the venereal disease division of the United States Public Health Service, many officials of both the Tuskegee Institute and its affiliated hospital, and hundreds of private physicians from the Macon County area.

Another frequently cited study in which the safety of human subjects was sacrificed in the interest of medical research was a project in the mid-1950's in which live hepatitis viruses were injected into retarded children living at Willowbrook on Staten Island, New York. Investigators justified the means used to carry out the research by noting that hepatitis ran rampant through the institution and a new resident would be likely to contract the disease within a few weeks after admission. Despite the fact that articles describing the study were widely circulated, the study continued until the early 1970's, even after the benefits of gamma globulin in the treatment of hepatitis had been established.

A third illustrative study took place in 1963 at the Jewish Chronic Disease Hospital in Brooklyn, New York. In that experiment doctors injected live cancer cells into twenty-two debilitated patients without their consent. This study and the public outcry that ensued provided the impetus for the Public Health Service's policy mandating institutional peer review of grant proposals prior to funding projects involving human subjects. These peer review committees have gradually evolved into the present day Institutional Review Boards which are regulated by the Department of Health and Human Services (HHS).

III. REGULATIONS GOVERNING INSTITUTIONAL REVIEW BOARDS

The National Research Act, enacted in 1974, directed the Secretary of Health, Education and Welfare (now HHS) to require that any entity applying for a grant to fund behavioral or biomedical research using human subjects provide an assurance that the entity had established an IRB to review all such research. The Act also created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was charged with the responsibility of evaluating the IRB system and making recommendations for changes

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* Id. See also J. Katz, *supra* note 2, at 1007-10.


* Gray & Cooke, *supra* note 6, at 37 (citing Curran, *Governmental Regulation of the Use of Human Subjects: The Approach of Two Federal Agencies*, 98 Daedalus 542-93 (Spring 1969)).


* The National Research Act was the popular name for Pub. L. No. 93-348, Title I, § 1 (1974) (codified at scattered sections of 42 U.S.C.). The section establishing IRBs was codified at 42 U.S.C.
in the regulations then in effect. The Commission conducted its study over a four year period, and published its findings and recommendations in 1978.\textsuperscript{10}

The current HHS regulations apply to all nonexempt research\textsuperscript{11} involving human subjects conducted by or funded by HHS.\textsuperscript{12} Although the Commission had recommended that the regulations be extended to cover research not funded by HHS\textsuperscript{13} but carried out in institutions receiving federal funds,\textsuperscript{14} this recommendation was not adopted.\textsuperscript{14} There were two primary reasons for not adopting the recommendation. First, the public response to the Commission's recommendation that the regulations be extended revealed "a broad based\textsuperscript{16} and significant amount of objection to the extension."\textsuperscript{17} Second, it was the opinion of the HHS General Counsel that "there is no clear statutory mandate in the National Research Act to support a requirement for IRB review of other than [HHS-funded] research."\textsuperscript{18}

The Commission's recommendations never specifically addressed the question of whether IRB members were liable for their actions, but apparently assumed that they were.\textsuperscript{19} This assumption was probably based on a section devoted to the legal aspects of IRB operation\textsuperscript{20} which appeared as a part of the Commission's report in the Federal Register. This report concluded that "IRB members may be personally liable to subjects and investigators for 'malpractice' or negligence in discharging their IRB functions."\textsuperscript{21}

The Commission recommended that the Secretary of HEW require that IRB members be provided with protection for any liability arising out of their duties.\textsuperscript{22} They commented that such protection could be provided by "sovereign immunity, insurance, indemnification by the institution, or specific provisions of state law."\textsuperscript{23}

\textsuperscript{11} Research involving educational tests, survey results, observations of public behavior, the collection of existing data, documents, and pathological or diagnostic specimens are exempt from regulation if they meet certain criteria, the most notable being that subjects are not readily identifiable from the data. 45 C.F.R. § 46.101(b) (1983).
\textsuperscript{12} Id. at § 46.101(a).
\textsuperscript{13} Many institutions conduct IRB review of all research without regard to the source of funding even though the HHS regulations do not require them to do so. 46 Fed. Reg. 8368 (1981).
\textsuperscript{15} Although HHS did not extend the regulations to cover non-HHS funded research as recommended by the Commission, HHS did urge institutions to voluntarily employ IRB review to protect human subjects participating in research not funded by HHS. 46 Fed. Reg. 8369 (1981).
\textsuperscript{16} The Commission did not explain their characterization of the objection as "broad based." The objection could have been the result of a strong lobbying effort on the part of research-oriented organizations.
\textsuperscript{17} 46 Fed. Reg. 8369 (1981).
\textsuperscript{18} Id.
\textsuperscript{20} Id. at 56,192.
\textsuperscript{21} Id. at 56,193.
\textsuperscript{22} Id. at 56,178.
\textsuperscript{23} Id. at 56,179.
This recommendation was not adopted when the new regulations were promulgated in January of 1981. HHS noted that it was hesitant to require such liability coverage because of the lack of mechanisms for providing it. Absent legislation, HHS left to the individual institution the choice of whether to provide liability coverage for IRB members. HHS also cited the lack of a single successful negligence action against an IRB member to support the contention that such protection would be both unnecessary and costly.24

The probability that IRB members would be liable for their negligence is reinforced by the regulations covering informed consent. The regulations provide that an informed consent document may not include any exculpatory language through which the subject is made to waive his legal rights against either the investigator, the sponsor, the institution, or its agents.25

The regulations also require, as part of informed consent, a statement regarding the availability of any compensation or medical treatment for injuries sustained by human subjects as a result of the research.26 Concern has been expressed by IRBs as to how to implement this regulation. Methods have varied among those institutions which have implemented compensation programs. The Office for Protection from Research Risks of the National Institute of Health has interpreted the regulation as not requiring compensation, but merely giving the prospective subject useful information in deciding whether to be a research participant.27

The University of Washington at Seattle has developed a system that compensates certain injured subjects.28 Reimbursement for lost wages is available to wage-earners, but not to unemployed subjects. While control subjects may receive free medical care, research patients may receive such medical care only if the injury is shown to be related to those procedures performed only for research, or in some cases, where an investigational drug or device is involved.29 Yale University School of Medicine also provides free medical therapy for those injuries caused by participation in the research, but not for those ordinarily expected in the course of customary medical treatment. However, no compensation is provided for lost wages.30 The University of California's scheme provides for medical treatment of injured subjects except when the injury resulted from a medical research procedure designed to benefit the subject directly.31

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26 Id. at § 46.116(a)(6).
27 Levine, Advice on Compensation: More Responses to DHEW's 'Interim Final Regulation,' IRB Apr. 1979 at 5 [hereinafter cited as Levine].
28 Id. at 5-6.
29 Id.
31 Levine, supra note 27, at 6.
Although such compensation programs might satisfy some injured subjects, others would not be deterred from seeking further compensation for lost wages, pain and suffering, mental distress, and perhaps punitive damages, through a lawsuit. These compensation schemes also offer no protection to an IRB member in the event of a suit by an investigator.

IV. Suits by Subjects

A. Opportunities for Negligence

Though a search of the literature reveals only one instance in which IRB members have been named as defendants in a suit, IRBs are in their neonatal stages, having only been required by law since 1976. Other types of peer review committees that have been in existence for longer periods of time have not escaped so easily, and it would be reasonable to predict that the incidence of suits against IRBs will increase in the future.

There are several points at which IRB members could be negligent in discharging their board duties. The first and perhaps the most difficult task an IRB undertakes when evaluating a research protocol is determining whether the research puts human subjects at risk, and if so, balancing the risks against the benefits to the subject and the knowledge to be gained from the research.

Of prime importance is the fact that the protocol presented to the IRB is normally prepared exclusively by the investigator. In his quest for knowledge or professional recognition, his interest in having the protocol approved may prompt him,

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12 The reported case that received fairly extensive media coverage was Head v. Colloton, 331 N.W.2d 870 (Iowa 1983), a suit filed by a leukemia victim challenging the decision of an IRB and naming its Chairman as a defendant. The case lends little to a discussion of how a court might decide a negligence action against an IRB, because the plaintiff sought only an injunction to compel the IRB to amend a protocol and no damages were requested. The case is interesting because, although the defendant argued throughout that the IRB's decision was arbitrary and capricious and unethical because it gave false hope to a dying man, both the district court and the Supreme Court of Iowa focused only on whether the records of a potential marrow donor were within the public domain. Courts may be reluctant to review an IRB decision because there is no firmly established precedent on which they can rely. See also Davis, Case Study: "Dear Mrs. X..." IRB Nov./Dec. 1983 at 6. In an unreported case, Bailey v. Mandel, No. 74-110 (D.C. Md. 1974), six prisoners from the Maryland State Penitentiary filed suit against an IRB chairman and various institution and state officials, alleging lack of informed consent in research projects utilizing prisoners as research subjects. The complaint asked for millions of dollars in damages, and the IRB chairman was one of between sixty and eighty named defendants. The court immediately dismissed the part of the complaint alleging inadequate review of research protocols and later completely dismissed the IRB chairman as a defendant. The case proceeded on a claim against the State of Maryland alleging that conditions within the prison were so bad that they violated the prisoners' constitutional rights.

13 45 C.F.R. § 46.111(a)(2) (1983) requires the IRB to determine that "[r]isks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."
consciously or subconsciously, to exaggerate the benefits and downplay the risks to the subject, thus violating his fiduciary duty\textsuperscript{34} to the subject.\textsuperscript{35} An IRB often includes members belonging to the same discipline as the petitioning investigator, and these members should recognize such misrepresentations. However, IRB members may be motivated to remain silent about perceived misrepresentations by the fear that rejecting a fellow worker's protocol will result in loss of friendships and ultimately create an unpleasant work environment. The problem is intensified when one realizes that the member remaining silent is the very person upon whom other board members will be depending to identify risks involved in the research. Silence on his part may be interpreted by the other board members as an assurance that he perceives minimal or no risks.

The difficulty in assessing the potential risks to research subjects versus the benefits to be gained cannot be overstated. Even if one assumes that the risks can be identified, there is no formula for assigning a value to them. The regulations provide little help, and the Commission has merely commented that the possible harms and benefits are to be evaluated systematically.\textsuperscript{36}

The study of IRBs, conducted by the Commission prior to making its recommendations, revealed that as the assessed risk of the research increased, so did the likelihood that the research would benefit the subject.\textsuperscript{37}

Table A\textsuperscript{38}

<table>
<thead>
<tr>
<th>Relative risk level*</th>
<th>Expected by investigator to benefit subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>No risk (N=710)</td>
<td>34</td>
</tr>
<tr>
<td>Very low risk (N=446)</td>
<td>52</td>
</tr>
<tr>
<td>Low risk (N=459)</td>
<td>63</td>
</tr>
<tr>
<td>Moderate risk (N=483)</td>
<td>80</td>
</tr>
</tbody>
</table>

*as assessed by investigators

If a project is deemed to have high risks and low benefits or, conversely, low risks and high benefits, the IRB's decision is simple. But should an IRB permit

\textsuperscript{34} A fiduciary relation is "[o]ne founded on trust or confidence reposed by one person in the integrity and fidelity of another." \textsc{Black's Law Dictionary} 564 (5th ed. 1979).


\textsuperscript{37} Id. at 56,188.

\textsuperscript{38} Adapted from 43 Fed. Reg. 56,180 (1978).
a human subject to be exposed to the possibility of death if there is a great chance
that if all goes well the quality of his life will be greatly enhanced? Conversely,
should a subject in excellent health be exposed to even a minimal risk if he can
expect little or no benefit from the research? Unfortunately, there are no clear-cut
answers to these questions, and the decisions must be made on a case-by-case basis.

The IRB member could also be negligent in assuring that "legally effective
informed consent" is obtained from the human subjects. Informed consent has
been the focus of much of the literature on research involving human subjects. The
Commission's study of IRBs concluded that although consent forms were
generally used, they tended to be incomplete. At the time the study was done,
the HEW regulations required fewer elements to be disclosed to the subject than
the current HHS regulations require. Components of informed consent at the
time of the study included six elements: the purpose of the research, the procedures
involved, the risks, the benefits, a statement that subjects were free to withdraw
from the research, and an invitation to ask questions. The study concluded that
only eighteen percent of the consent forms were complete or nearly complete, and
information conveyed orally to subjects by investigators improved the statistics only
negligibly. The incidence of each of the required items not being included was as
follows:

<table>
<thead>
<tr>
<th>Element</th>
<th>Percent of Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excluding Element</td>
<td></td>
</tr>
<tr>
<td>Procedures</td>
<td>10</td>
</tr>
<tr>
<td>Purpose</td>
<td>23</td>
</tr>
<tr>
<td>Benefits to subjects</td>
<td>45</td>
</tr>
<tr>
<td>Risks to subjects</td>
<td>30</td>
</tr>
<tr>
<td>Statement regarding withdrawal</td>
<td>22</td>
</tr>
<tr>
<td>Offer to answer questions</td>
<td>Less than 50</td>
</tr>
</tbody>
</table>

19 45 C.F.R. § 46.116 (1983). An analysis of informed consent begins with the principal that
"[e]very human being of adult years and sound mind has a right to determine what shall be done
with his own body . . . ." Schloendorff v. Society of New York Hosp., 211 N.Y. 125, 105 N.E. 92,
93 (1914). In determining a standard for informed consent to medical treatment, the majority of courts
for years made the duty of the physician dependent on the custom of physicians practicing in the community. The trend is now toward a standard which requires the scope of the physician's communications to the patient to be measured by the patient's need of information material to the decision to be made. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972). Cobbs v. Grant, 8 Cal.3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (1972).

40 See generally ANNAS, GLANTZ, & KATZ, INFORMED CONSENT TO HUMAN EXPERIMENTATION (1977).
The study also concluded that a description of alternate treatments available to the subject was mentioned in less than twenty percent of the cases and the "experimental" nature of the research was mentioned in only forty percent of the consent forms.44

The Commission's study also computed the readability of each consent form and found that only fifteen percent of the forms were in language as simple as that found in Time magazine.45 The principal problem was the excessive use of medical or technical jargon not readily understood by the average lay person. Generally, those forms which IRBs had required investigators to modify were no more readable or complete than those approved as originally submitted.

Although IRBs ordinarily lack the time and staff to evaluate and edit consent forms, an IRB may be liable for negligently performing its duty if it approves a form that is inadequate. One solution is for an IRB to issue specific guidelines to investigators within the institution, outlining the type of consent forms required for protocol approval, and to couple these with staunch enforcement measures. This will put the burden on the investigator, who only has to tailor a single form, rather than on the IRB which may review hundreds of such forms each year.

The regulations governing IRBs now contain a longer list of information that must be provided to a human subject as part of the consent process than the items required when the Commission conducted its study. Items to be provided include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments

44 Id.
45 Id.
are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.46

In addition, an IRB must decide if the research is of a type which warrants the inclusion of any of the following six other items of information:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.47

This extensive list of items to be monitored by an IRB multiplies the amount of time it would take an IRB to modify a proposed form that did not conform to the requirements. Requiring investigators to perform this task would permit an IRB to spend a greater amount of time on its more important duties, such as assessing risks to subjects.

The HHS regulations enacted in January of 198148 permit an IRB to approve a consent form which does not include all of the elements of informed consent, or to waive the requirement of informed consent altogether, if the IRB determines

47 Id. at § 46.116(b)(1)-(6).
48 Id. at § 46.116.
that only minimal risk is involved, and the altered procedure is necessary to carry out the research. If the board incorrectly assesses the risks as minimal, another potential source of liability arises.

As the Commission pointed out in the comments following its recommendations "[t]he documentation of consent (i.e. the consent form) should never be confused with the substance of informed consent." A consent form that rigidly complies with the elements set forth in the regulations is not dispositive of the issue of whether consent was "informed." In addition to its task of approving a consent form, the HHS regulations require an IRB to assure that an investigator seek consent "only under circumstances that provide the prospective subject . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." In reality, an IRB does not normally have the staff to assure than an investigator has complied with this mandate, and must rely on the good faith of the investigator.

Although the regulations authorize members of an IRB, or a third party designated by them, to observe the consent process, a recent poll of one hundred IRB members revealed that only two had ever required anyone other than the investigator to take part in obtaining informed consent. Too much is left to the investigator whose interest in obtaining subjects for his research may overshadow the goal of assuring that the subject has knowingly and voluntarily consented.

Medical research often requires as subjects those afflicted with the disease being studied. Given the debilitated condition of these patients and the emotional strain they are under, they may be too willing to consent to participation. The substantial amount of trust and confidence that the average person places in a doctor may also tip the scales in favor of consent. When debilitated patients are the potential research subjects, an IRB may be negligent for failing to take the extra precautions of having a board member or a third party observe the consent process.

IRB members may also be negligent in performing another duty imposed on them by the regulations: conducting "continuing review of research . . . at intervals appropriate to the degree of risk, but not less than once per year . . . ." Since one year intervals are imposed as a minimum, one can assume that high risk research is meant to be reviewed much more frequently. In its study of IRBs from 1974 until 1978 the Commission found that only half of the boards had a policy requiring an investigator to report subject injuries to the board. A little over one-

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49 Id. at § 46.116(c)-(d).
52 Id. at § 46.109(e).
third of the boards studied had ever designated someone to observe the research project and only half of this group did so routinely.\textsuperscript{55}

In the extreme, one might envision continuing review of research as including compliance officers visiting the researcher's workplace and recording detected violations of the approved protocol. Review could be interpreted to include viewing the procedures utilized, inspecting records and perhaps interviewing the research subjects. Unless such an interpretation is spelled out in the regulations, most institutions would be likely to opt for a less burdensome construction of the term "continuing review" and require a yearly report for all research except that involving more than a moderate amount of risk. One commentator has suggested that IRBs delegate this monitoring function to department heads who are normally already responsible for overseeing projects within their department.\textsuperscript{56} The inherent problem in this solution is that department heads often share the research-oriented attitudes of the investigator and may not be true advocates of subject protection.

Between the extremes of a method involving costly procedures to train compliance officers and set up offices for record keeping, and a method requiring only token yearly reports, there are approaches an IRB can take to ensure an effective continuing review. For example, each IRB could have a policy requiring an investigator to report subject illnesses, injuries, and other untoward effects to the IRB, as they occur, with an indication of whether this is the first incidence of such an event associated with the project. The IRB could evaluate the report and decide whether the incident warranted a full review of the project.

When HHS adopted its 1981 version of the regulations governing research using human subjects, one of the major changes was a provision allowing expedited review of certain projects involving only minimal risk.\textsuperscript{57} The provision authorizes either the chairperson of an IRB or an experienced member of the board to approve (but not to disapprove) those projects which qualify for expedited review.\textsuperscript{58}

The efficacy of this procedure depends on the ability of one reviewer to determine whether only minimal risk is entailed. Although the Secretary has published a list of categories that qualify for expedited review,\textsuperscript{59} some of these are vaguely worded and leave ample room for error on the part of the IRB member. One such category is "[r]esearch on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress for subjects."\textsuperscript{60} Although such research generally presents

\textsuperscript{57} 45 C.F.R. § 46.110 (1983).
\textsuperscript{58} Id. at § 46.110(b).
\textsuperscript{60} Id.
little or no danger of physical injury, the potential for psychological harm is often a factor. HHS stated in the discussion of its new regulations that the categories it has approved as being subject to expedited review are to be narrowly defined.\textsuperscript{61} Thus it appears that if an IRB has any doubts about whether a protocol falls within one of the categories which qualify for expedited review, it should decide in favor of full review.

The regulations also require that each member of the IRB be kept advised of those protocols approved by expedited review.\textsuperscript{62} What then is the duty of those members who did not participate in the expedited review but have doubts about whether the project should have been approved? The Commission recommended that any member who received notice that a project had been approved by expedited review should be able to demand a full review of the protocol by the IRB.\textsuperscript{63} Although HHS essentially adopted the rest of the Commission’s recommendations for expedited review it omitted “the requirement that all IRB members be promptly notified of protocols approved by expedited review and be able to request full committee consideration.”\textsuperscript{64} HHS gave no reason for not adopting this part of the recommendation.

B. Elements of the Case

Because “the whole theory of negligence presupposes some uniform standard of behavior,”\textsuperscript{65} it would seem likely that IRB members, if sued for negligent performance of their board duties, will be held to a standard of due care.\textsuperscript{66} The pertinent question may be, who is the “reasonable man” to whom a member will be compared? Considering the diversity of expertise of members within a single IRB,\textsuperscript{67} certain members may be held to a higher standard than others. An IRB member whose expertise is in the same field as the investigator whose protocol is being reviewed might be aware of risks which the investigator has not disclosed. In such an instance, the member could be held liable for information which he knew, or should have known, in light of his special skill or knowledge.\textsuperscript{68}

\textsuperscript{61} Id. at 8380.
\textsuperscript{62} 45 C.F.R. § 46.110(c) (1983).
\textsuperscript{65} W. PROSSER, HANDBOOK OF THE LAW OF TORTS, § 32 (4th ed. 1971) [hereinafter cited as PROSSER].
\textsuperscript{66} Robertson, supra note 1. See generally PROSSER, supra note 65.
\textsuperscript{67} The HHS regulations require that each IRB shall include at least five members with varying backgrounds. Both men and women must be included and no IRB may consist entirely of members of one profession. One member’s concerns must be primarily nonscientific and at least one member must be neither affiliated with the institution nor part of the immediate family of a person affiliated with the institution. 45 C.F.R. § 46.107(a)-(d) (1983).
\textsuperscript{68} PROSSER, supra note 65, at 161-66.
A lay member or one who possesses no special expertise in the field being reviewed still has the responsibility of being "conscious of his own ignorance."\textsuperscript{69} His duty to the human subjects he seeks to protect may require him to "know at least enough to conduct an intelligent inquiry as to what he does not know."\textsuperscript{70}

The regulations governing IRBs give the board the authority to "invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB."\textsuperscript{71} This authority may eliminate any ignorance defense the board may have had when no board members were within the same discipline as the investigator whose protocol was being reviewed. A court might find that the board was negligent in failing to utilize an expert to explain the procedures involved where board members did not possess the requisite understanding to allow them to assess the potential risks.

The burden of proving the member's negligence will be on the injured subject.\textsuperscript{72} The subject will also bear the burden of proving "causation in fact":\textsuperscript{73} that the act or omission of the IRB member is reasonably connected to the injury which the subject has suffered.\textsuperscript{74} Especially in the field of medical research, this will be a difficult burden. Many human subjects are included in a study because they are victims of the disease being studied. They are in a debilitated state to begin with, and the prognosis is often poor. The worsening of such a subject's condition can often be just as easily attributed to the disease itself as to the research procedure.

In proving causation the subject must show that it is more likely than not that the IRB's negligence was a substantial factor in bringing about his injury.\textsuperscript{75} Nevertheless, a court may find that the researcher was an "intervening cause" and absolve the IRB of responsibility. A decision by a court that an event was an intervening cause is essentially a policy decision as to whether a "defendant is to be held liable for an injury to which he has . . . made a substantial contribution, when it is brought about by a later cause of independent origin, for which he is not responsible."\textsuperscript{76}

Although the IRB may have negligently failed to recognize a potential risk or negligently assessed its consequences, the court may find that the injurious result would not have been realized without the subsequent negligence of the researcher. However, the IRB will not necessarily be relieved from liability when a risk to which the IRB has exposed a subject has come to pass.\textsuperscript{77} If the intervening cause is one

\textsuperscript{69} Id. at 160.
\textsuperscript{70} Id.
\textsuperscript{71} 45 C.F.R. § 46.107(f) (1983).
\textsuperscript{72} PROSSER, supra note 65, at 208-09.
\textsuperscript{73} Id. at 241.
\textsuperscript{74} Id. at 236.
\textsuperscript{75} Id. at 241.
\textsuperscript{76} Id. at 270.
\textsuperscript{77} Id. at 273.
which the IRB had reason to anticipate under the particular circumstances, the board may be negligent for exposing the victim to the risks. 78

In many cases this proof will require expert testimony, thus increasing the cost of litigation. This may discourage a potential plaintiff from pursuing a lawsuit and may discourage the plaintiff's attorney from accepting the case on a contingent fee basis. Medical expert testimony is not only expensive, but also problematic. It may be difficult or impossible to persuade a doctor to testify to another's negligence.

C. Defenses to a Suit

Where an IRB serves an institution which is an agent of the state, the doctrine of sovereign immunity may protect both the institution and the IRB members as agents of the institution. 79 However, sovereign immunity varies among the states, and since 1957 has been subject to gradual erosion, 80 either by statutes through which a state accepts tort liability or by judicially created exceptions. 81

West Virginia is one of the states which has not completely abrogated sovereign immunity. 82 Because this immunity is within the state constitution, abrogation of the immunity would require an amendment to the constitution. 83 However, the legislature has limited the effects of the doctrine by the creation of the court of claims, 84 which recognizes a moral obligation on the part of the state to compensate injured parties for those injuries caused by agents or employees of the State who are engaged in governmental activities. 85

A second attempt by the West Virginia Legislature to mitigate the harsh effects of sovereign immunity was the creation of a state board of insurance 86 which is

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78 Id. at 272.
80 PROSSER, supra note 65, at 985-87.
81 For positions of the various states on sovereign immunity see RESTATEMENT (SECOND) OF TORTS § 895B (1982).
82 W. VA. CONST. art. VI, § 35 reads:
The state of West Virginia shall never be made defendant in any court of law or equity, except the state of West Virginia, including any subdivision thereof, or any municipality therein, or any officer, agent, or employee thereof, may be made defendant in any garnishment or attachment proceeding, as garnishee or suggestee.
83 W. VA. Const. art. XIV § 2 provides that a proposed amendment be agreed to by two-thirds of the members of each house on its third reading and then submitted to the voters of the State for ratification by a majority at a special or general election.
authorized to negotiate and settle any insurance claims arising from activities and services of State agents and employees.\textsuperscript{87}

Through the years, the West Virginia Supreme Court of Appeals has also carved out exceptions to the prohibition against suing the State,\textsuperscript{88} but has "adhered to the position that bona fide state agencies\textsuperscript{89} are immune from damage suits . . . ."\textsuperscript{90} The most recent of these holdings announced that when recovery is sought under the State’s liability insurance coverage, the doctrine of constitutional immunity is simply inapplicable.\textsuperscript{91}

There is also the possibility that members of hospital based IRBs would come within the protection of state statutes which provide immunity to members of hospital and medical staff review committees.\textsuperscript{92} These statutes vary widely, some protecting only physicians and others extending coverage even to those who merely provide information to the committee.\textsuperscript{93} These statutes do not preclude litigation altogether; such questions as whether physicians were acting without malice are to be decided by the jury.\textsuperscript{94}

Members of an IRB who did not participate in expedited review of a proposal cannot simply claim nonparticipation as a defense. By way of analogy, if those members of an IRB who did not participate in expedited review were members of a corporate board of directors, they would not necessarily be insulated from liability simply because they had not participated in the decision. Section 42 of the Model Business Corporation Act (MBCA) allows the board of directors to ap-

\textsuperscript{87} W. VA. CODE § 29-12-5 (1980).
\textsuperscript{88} For a collection of cases in which the West Virginia courts have held various agencies of the state to be amenable to suit, see Pittsburgh Elevator v. West Virginia Bd. of Regents, 310 S.E.2d 675, 685-86 (W. Va. 1983).
\textsuperscript{90} Pittsburgh Elevator v. West Virginia Bd. of Regents, 310 S.E.2d 675, 687 (W. Va. 1983).
\textsuperscript{91} Id. at 689.
\textsuperscript{89} These committees attempt to ensure that high quality care is delivered to patients in the hospital. They fulfill this goal by reviewing the credentials and performance of those applying for medical staff positions and also of those members of the staff who seek reappointment or wish to expand their clinical privileges. Hall, Hospital Committee Proceedings and Reports: Their Legal Status, 1 AM. J.L. & MED. 245 (1975) [hereinafter cited as Committee Proceedings].
\textsuperscript{93} Committee Proceedings, supra note 92, at 262-64. For a discussion of West Virginia statute providing immunity to health care peer review organizations, see infra text accompanying notes and W. VA. CODE § 30-3C-2 (1980 & Supp. 1983).
\textsuperscript{94} Committee Proceedings, supra note 92, at 262 & n.55 (citing Ascherman v. San Francisco Medical Society, 39 Cal. App.3d 623, 114 Cal. Rptr. 681 (1974)).
point committees which may exercise the full authority of the board (subject to certain exceptions) and further provides that

[n]either the designation of any such committee, the delegation thereto of authority, nor action by such committee pursuant to such authority shall alone constitute compliance by any member of the board of directors, not a member of the committee in question, with his responsibility to act in good faith, in a manner he reasonably believes to be in the best interests of the corporation, and with such care as an ordinarily prudent person in a like position would use under similar circumstances.93

Section 35 of the MBCA, in essence, affords a board member the right to rely on opinions or reports prepared by a committee of the board without imposing liability upon the member for his reliance.96 By further analogy, the IRB member who relies on the opinion of the member conducting expedited review would not be liable for his acquiescence in the decision. However, an IRB member whose special expertise alerts him to potential risks in the protocol might not escape liability using the MBCA analogy, because section 35 of the Act further states that the board member "shall not be considered to be acting in good faith if he has knowledge concerning the matter in question that would cause such reliance to be unwarranted."97

D. Conclusion

The inescapable conclusion is that if an institution wants its IRB to comply with all of the previously cited, pertinent duties, the institution must be willing to expend the resources needed to staff the IRB sufficiently to carry out those duties. At the institutional level this may involve a decision as to whether it is more economically efficient to provide the IRB with the resources required to adequately perform its duties, or to defend lawsuits as they arise. Considering the current lack of suits by human subjects against an IRB, the institution making such an economic analysis will probably choose the latter.

Where does this leave the individual IRB member? Unless the institution has provided insurance covering the member or has contracted to indemnify him, an IRB member may have to defend a suit brought against him individually (in addition to the suit against the institution) and use personal funds to pay the costs of litigation and perhaps the costs of a judgment against him. Members presently on boards would be wise to insist on financial protection against liability as a condition of further service as a board member.

93 MODEL BUSINESS CORP. ACT § 42 (1980).
96 MODEL BUSINESS CORP. ACT § 35 (1980).
97 Id.
V. SUITS BY INVESTIGATORS

In addition to suits by injured subjects, IRB members also face the potential of suits by investigators whose protocols have been disapproved or who feel they have not been treated fairly by the IRB.

The commission’s survey of IRBs, which was included in its 1978 report, concluded that there may be a trade-off between IRB activity and investigator acceptance.98 Those IRBs which more frequently required modification of protocols or requested additional information received less favorable evaluations by investigators.99 Forty-nine percent of behavioral and social scientists and fifty percent of biomedical scientists at institutions included in the study agreed with a statement that IRBs got into areas not appropriate to their function.100 Although the Commission’s survey found that about seventy percent of IRB members were biomedical or behavioral scientists,101 there was a feeling among a substantial minority of investigators whose protocols had been reviewed that the review process was an unwarranted intrusion upon an investigator’s autonomy.102

A reading of the federal regulations governing research on human subjects reveals that the function of an IRB is to protect human subjects; nowhere is it mentioned that an alternate function is to facilitate research. The regulations cannot effectively operate without limiting the autonomy of a researcher, but because a compelling state interest is at stake, this intrusion could hardly be classified as unjustified. Nevertheless, investigators who view IRB review as an unwarranted intrusion upon their autonomy may seek recourse through lawsuits.

A. Deprivation of Academic Freedom

Investigators could argue that IRB review results in a deprivation of academic freedom. The extent of the right to do research depends in large measure upon whether the courts recognize a constitutional basis for the right. Grounding the right in the Constitution subjects any attempted governmental regulation of the right to stricter scrutiny and requires the government to demonstrate a compelling state interest justifying intervention.103 Although they have not yet been presented with the issue, the courts could recognize a right to do research under the first amendment.104 Although the first amendment is traditionally considered to protect speech, courts have held that “when ‘speech’ and ‘nonspeech’ elements are com-

99 Id.
101 Id. at 56,187.
102 Id. at 56,191.
104 Id. See also 43 Fed. Reg. 56,192 (1978).
bined in the same course of conduct, a sufficiently important governmental interest in regulating the nonspeech element can justify incidental limitations on the First Amendment freedoms.\textsuperscript{105} The courts may find that collecting data through research could qualify as the nonspeech element of conduct, with publication of the research being the speech element of the same course of conduct. Thus, while a researcher could argue that IRB review impinges on his first amendment right to publish the results of his research, the court could hold that the protection of the human subjects involved in the research justifies the limitations placed on his right to publish.

The right of the researcher to choose the means to carry out research is less absolute than the right to select the topic or research goal.\textsuperscript{106} While selection of a topic involves planning and creativity on the part of the investigator, the means used to carry out the research will normally involve the physical and emotional health and safety of those who agree to participate in the research. Along with any constitutional right comes potential government regulation if the exercise of that right conflicts with a substantial public interest. The protection of the health and safety of the populous has been held to be a sufficiently important interest to justify government intervention.\textsuperscript{107}

When a researcher is compelled to subject his research proposals to IRB approval as a condition of employment or as a condition to funding, constitutional limitations do not apply even as to the research topic.\textsuperscript{108} Neither the government nor an institution has any legal obligation to support research that it deems unimportant or inappropriate.\textsuperscript{109} Allocation of funding is within the broad discretion of an institution or government agency and absent discrimination against a protected class, an investigator has no claim to a share of those funds. Thus, an institution may delegate to an IRB the task of screening both the proposed research topics and the means to carry out the research.

B. Interference with Contract

An investigator who feels that IRB review was unwarranted could bring a suit against an IRB alleging tortious interference with contractual relations. Traditionally, six elements of the tort have been recognized:

(1) the existence of a contract\textsuperscript{110} or a legally protected interest between the plaintiff and a third party;


\textsuperscript{106} Right to Research, supra note 103, at 1206.

\textsuperscript{107} See generally L. Tribe, American Constitutional Law (1978).


\textsuperscript{109} Id.

\textsuperscript{110} Although there has been considerable disagreement as to whether contracts terminable at will should be actionable, the trend is to allow a cause of action since, until it is terminated, the contract is a valuable relation between the plaintiff and the third party. Prosser, supra note 65, at 932. See also Alpha Distribe Co. v. Jack Daniel Distillery, 454 F.2d 442,450 (9th Cir. 1972), aff’d mem. after remand, 493 F.2d 1355 (9th Cir.), cert. denied, 419 U.S. 842 (1974).
(2) the defendant's knowledge of the contract;
(3) the defendant's intentional inducement of the third party to breach or otherwise render impossible the performance of the contract;
(4) without justification on the part of the defendant;
(5) the subsequent breach by the third party; and
(6) damages to the plaintiff resulting therefrom.\textsuperscript{111}

Historically, success in these suits depended on the plaintiff showing the defendant's motive or purpose to be malicious. The term "malicious" as it applies to the tort of interference with contractual relations has gradually come to mean legal malice,\textsuperscript{112} rather than actual malice.\textsuperscript{113} Hence, malice may be implied by showing knowledge of the existence of a contract.\textsuperscript{114} Today, if the plaintiff can show that the defendant intentionally interfered with contractual relations between the plaintiff and a third party, he has established a prima facie case for liability.\textsuperscript{115} The burden then shifts to the defendant to show that the interference was justified.\textsuperscript{116}

In the case of an IRB review, a plaintiff will not be able to easily demonstrate the intent needed to establish a prima facie case. Absent some ulterior motive on the part of an individual member, an IRB has no interest in the investigator's contract with a third party. The IRB functions only to ensure that the human subjects are not put at risk by the research methods proposed. Any effect that the IRB's decision has on an investigator's contract with a third party is incidental and would not be likely to satisfy the requirement of intent.

Interference with contract has remained almost entirely an intentional tort and attempts to extend it to negligence have been unsuccessful, primarily because courts have found a lack of proximate cause.\textsuperscript{117} This is essentially a policy decision by

\textsuperscript{111} 3 DOOLEY, MODERN TORT LAW § 44.03 (1983) [hereinafter cited as DOOLEY]. See also Hannigan v. Sears, Roebuck and Co., 410 F.2d 285, 291 (7th Cir.), cert. denied, 396 U.S. 902 (1969); Republic Gear Co. v. Borg-Warner Corp., 406 F.2d 57, 61 (7th Cir.), cert. denied, 394 U.S. 1000 (1969); National Gas Appliance Corp. v. Manitowac Co., 311 F.2d 896, 899 n.5 (7th Cir. 1962) (citing Northern Ins. Co. of N.Y. v. Doctor, 23 Ill. App. 2d 225, 228, 161 N.E.2d 867, 869 (1959)).

\textsuperscript{112} Malice in law is "[t]he intentional doing of a wrongful act without just cause or excuse . . . [t] is presumed from tortious acts, deliberately done without just cause, excuse, or justification, which are reasonably calculated to injure another or others." BLACK'S LAW DICTIONARY 863 (5th ed. 1979).

\textsuperscript{113} DOOLEY, supra note 111, at § 44.06.

Actual or express malice is "ill will or wrongful motive. A deliberate intention to commit an injury, evidenced by external circumstances." BLACK'S LAW DICTIONARY 862 (5th ed. 1979).

\textsuperscript{114} DOOLEY, supra note 111, at § 44.06.

Malice in the sense of intending actual harm because of spite or ill feeling is, of course, not a requisite to the tort of inducing breach of contract [citation omitted]. Knowledge of the existence of the contract is enough and implies malice.

the courts not to hold the defendant liable for the remote consequences of an act.118 Thus, if an IRB caused an investigator to lose a contract with a third party because it overestimated the risk to human subjects and disapproved a protocol that should have been approved, the negligence of the board will not subject the IRB to liability for interference with contractual relations.

Suits alleging interference with contractual relations are currently analyzed by "balancing the conflicting interest of the parties, and determining whether the defendant's objective shall prevail at the expense of . . . harm to the plaintiff."119 If the defendant can show that the interests he seeks to further make his conduct privileged he may be protected from liability.120 "An impersonal or disinterested motive of a laudable character may protect the defendant . . . particularly where he seeks to protect a third person toward whom he stands in a relation of responsibility."121

Either the investigator or the party with whom the investigator had a contract could bring a suit alleging interference with contractual relations. The third element of the tort requires that the IRB intentionally induce the third party to breach or otherwise render impossible the performance of the contract.

Because the IRB normally does not have contact with the third party, such as a drug company who has contracted with the investigator, it can hardly be argued that the IRB has induced the drug company to breach the contract. Therefore, it would seem more appropriate for the drug company to bring the suit alleging that the IRB induced the investigator to breach by rendering his performance impossible.

On the other hand, the investigator could bring suit on the grounds that the IRB has indirectly caused the drug company, which then would become the third party, to breach the contract, because although the investigator was ready and willing to perform he could not do so without IRB approval.

Because of the absence of a body of case law relating to IRBs, this Note will attempt to form an analogy using suits brought against hospital peer review committees. Both IRBs and hospital review committees have as a common purpose the protection of the health and safety of the public. To achieve this purpose, candid discussion is necessary when both IRBs and hospital review committees meet. Both types of review committees are at least partially composed of members who work in the same institution as the individual seeking review. Members may fear that any unfavorable comments they make will have a detrimental effect upon their working relationship with the investigator/doctor unless there is some protection against disclosure. These past suits involving members of hospital review committees bear sufficient similarities to potential suits against IRB members to warrant analogy.

118 Id.
119 Id. at 928.
120 Id. at 943.
121 Id.
In the 1983 case of Qasem v. Kozarek,\textsuperscript{122} a physician sued members of a hospital’s credentials committee alleging tortious interference with his contract with the hospital. After Qasem had held staff privileges for two years, the credentials committee recommended that he no longer be permitted to perform certain surgical procedures. At the trial level, a jury found for the plaintiff and awarded $32,000.00 in compensatory damages.\textsuperscript{123}

Wisconsin’s peer review statute\textsuperscript{124} was the focus of the court’s analysis on appeal. This statute protected members of the committee, provided that they acted in good faith. The statute described “good faith” as not preventing the physician or his lawyer from examining documents used in the review process, from presenting witnesses in his behalf, from cross-examining adverse witnesses, from refuting testimony or evidence, nor from receiving a copy of the recommendation adopted by the committee.\textsuperscript{125} The trial court’s instructions to the jury defined good faith only in common law terms such as dishonesty, fraud, and the significant disregard of the interest of another and ignored the definition set out in the statute.\textsuperscript{126}

The Seventh Circuit, after examining the legislative history of the statute, concluded that a member of the review committee could still be found to have acted in bad faith under the common law standard\textsuperscript{127} even if the procedural rights set out in the statute were not denied. However, whether these procedural rights were denied was a factor that must be considered in determining whether he acted in bad faith.\textsuperscript{128} The court reversed and remanded for a new trial.\textsuperscript{129}

C. Defamation

An investigator could also sue an IRB member for defamation arising out of statements about the investigator made by the member to the IRB. Defamation is a communication to a third person ‘which tends to injure ‘reputation’ . . . to diminish the esteem, respect, goodwill or confidence in which the plaintiff is held, or to excite adverse, derogatory or unpleasant feelings or opinions about him.’\textsuperscript{130} If the communication to the third person is oral, the resulting tort is slander.\textsuperscript{131} Although slander in general is not actionable unless the plaintiff can prove some

\begin{itemize}
  \item \textsuperscript{122} Qasem v. Kozarek, 716 F.2d 1172 (7th Cir. 1983).
  \item \textsuperscript{123} Id. at 1175.
  \item \textsuperscript{124} Wis. Stat. § 146.37 (1981-82).
  \item \textsuperscript{125} Id.
  \item \textsuperscript{126} Qasem, 716 F.2d at 1179.
  \item \textsuperscript{127} Bad faith is defined as “implying or involving actual or constructive fraud, or a design to mislead or deceive another, or a neglect or refusal to fulfill some duty or some contractual obligation, not prompted by an honest mistake as to one’s rights or duties, but by some interested or sinister motive.” BLACK’S LAW DICTIONARY 127 (5th ed. 1979).
  \item \textsuperscript{128} Id. at 1178.
  \item \textsuperscript{129} Id. at 1180.
  \item \textsuperscript{130} PROSSER, supra note 65, at 739.
  \item \textsuperscript{131} Id. at 737.
\end{itemize}
actual damage, one of the exceptions to this general rule is slander which affects the plaintiff in his business, trade or profession.\textsuperscript{132} If conduct falls within this exception, a jury is permitted to estimate the damage without any proof of its existence.\textsuperscript{133} This exception, however, is limited to cases where the content of the defamation is incompatible with the qualities the public expects of one of the calling in which the plaintiff is engaged.\textsuperscript{134}

Rather than requiring intent or even negligence, defamation is a strict liability tort and the absence of ill will becomes an issue only if the defendant asserts the defense of qualified privilege.\textsuperscript{135} The defense of privilege may be applied if the defendant is acting in pursuit of some public interest which clearly overrides the harm to the plaintiff’s reputation.\textsuperscript{136} Although IRBs would not qualify for an absolute immunity from suit, society’s interest in promoting frank and open discussion at review sessions to assure adequate protection for human subjects would merit a qualified privilege. However, even when a defendant is eligible for a qualified privilege, the court will examine his motive. If the court finds that the primary purpose for the defamation is not to protect the interest the defendant is entitled to protect, the privilege may be forfeited.

In Matvieuw v. Johnson,\textsuperscript{139} a physician brought suit against a colleague who testified before a medical center executive committee concerning the physician’s alleged incompetence and unethical practices. The trial court dismissed the complaint, holding the defendant’s remarks to be absolutely privileged.\textsuperscript{140} The Appellate Court of Illinois reversed,\textsuperscript{141} according only a qualified privilege to those testifying before a hospital executive committee. While recognizing the need for candid conversations in such committee meetings, the court succinctly stated that “[d]efamatory statements, motivated by ill-will or malice, have no place in a forum convened to determine the qualifications of an individual to continue in the practice of his profession.”\textsuperscript{142}

Not all states have enacted statutes granting qualified immunity to review committees, and those enacted vary as to the scope of immunity.\textsuperscript{143} While some statutes grant immunity only to physicians on review committees required by Medicare and

\textsuperscript{132} Id. at 754.
\textsuperscript{133} Id.
\textsuperscript{134} Id. at 757-59.
\textsuperscript{135} Id. at 771-72.
\textsuperscript{136} Id. at 776.
\textsuperscript{137} Id. at 777-85. Absolute immunity has been limited to situations which involve judicial proceedings, legislative proceedings, executive communications, consent of the plaintiff, husband and wife, and political broadcasts.
\textsuperscript{138} Id. at 795.
\textsuperscript{140} Id. at 797.
\textsuperscript{141} Id. at 800.
\textsuperscript{142} Id. at 799.
\textsuperscript{143} Committee Proceedings, supra note 92, at 262.
Medicaid programs, others, such as the Ohio statute at issue in *Samuelson v. Susen,* accord immunity to those providing a review committee with information.

West Virginia's statute provides for immunity against suits brought by one whose activities are being reviewed, but only for members who have acted without malice or gross negligence. Although the statute, as originally written, required the exercise of due care, a 1980 amendment substituted an absence of gross negligence as the standard. Absence of malice, however, was included in both versions. The statute also protects those persons providing information to the review committee provided that the information is relevant to the task the committee seeks to perform. The person will not be protected for providing information which he knew or had reason to know was false.

In litigating a suit for defamation against an IRB member, the plaintiff investigator might be forced to rely on evidence other than minutes and records of the IRB meeting at which the alleged defamation occurred. Many states have enacted statutes protecting the reports of hospital review committees from discovery. The statutes vary widely from state to state.

In *Samuelson v. Susen,* a case challenging Ohio's statute, a neurosurgeon sought to depose physicians and hospital administrators in a suit alleging defamation and tortious interference with business and professional relationships. The allegedly defamatory statements had been made during a committee review of his application for staff privileges. The Ohio statute not only barred discovery of the records of the review committee meetings in civil actions arising out of matters reviewed, but also barred those in attendance from testifying about what had transpired at such meetings. The plaintiff argued that the statute was designed to prevent discovery in malpractice cases and should not be applied "against a physician whose opportunity to practice is being restrained." The court rejected both this argument and further claims of deprivation of due process rights and held that the deponents fell within the protection of the statute.

In *Auld v. Holly,* a physician who was denied staff privileges brought a

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146 W. VA. CODE § 30-3C-2(b) (1980).
147 W. VA. CODE § 30-3C-2(b) (Supp. 1983).
149 Id. at § 30-3C-2(a)(2) (1980 & Supp. 1983).
150 *Committee Proceedings,* supra note 92, at 274. This article cites a 1975 source which concluded that twenty-two states had enacted such statutes. Thirteen of these states had barred such proceedings and reports from subpoena, discovery, or disclosure while nine of these states had enacted less protective statutes.
151 *Samuelson,* 576 F.2d 546.
153 *Samuelson,* 576 F.2d at 552.
154 Id. at 552-53.
defamation action against members of the hospital's credentials committee. The plaintiff sought discovery of the committee's records and sought to question witnesses. The trial court denied discovery on the basis of a Florida statute\textsuperscript{156} regulating discovery of proceedings and records of medical review committees.\textsuperscript{157} The District Court of Appeal reversed,\textsuperscript{158} holding that the discovery privilege accorded by the statute applied only in cases where a physician was sued for malpractice in the delivery of health services. Noting that tort immunity applied to committee members only in the absence of fraud or malice, the court reasoned that "the Legislature would not have authorized a cause of action against a committee member for fraud and malice and yet barred discovery of the evidence necessary to maintain the action."\textsuperscript{159} On appeal, the Florida Supreme Court reversed, holding that the statute's bar against discovery of the medical review committee's records was not limited to actions based on medical malpractice.\textsuperscript{160} The court assumed that the legislature had balanced the potential detriment to the discovery rights of civil litigants against the potential benefit to health care cost containment which results from self-regulation through peer review and found the latter to be of greater weight. The court deemed it inappropriate to interfere with this decision which was exclusively the province of the legislature. The court also stated that the need for confidentiality is as great when a committee is evaluating a physician for staff privileges as when measuring the doctor's conduct against the standards of the medical community in a malpractice suit.

Conversely, other states have statutes that only limit discovery in medical malpractice cases and are not applicable in suits for defamation brought against members of a hospital review committee. The West Virginia statute\textsuperscript{161} protects the proceedings and records of a review committee from subpoena or discovery and bars the testimony in a civil action of any person in attendance at a review committee meeting.\textsuperscript{162} However, the statute further provides that if one whose activities have been reviewed brings a civil action, the otherwise protected materials shall be available to the individual.\textsuperscript{163}

There is much room for debate as to which is the better view. On one side is the unfortunate plight of a doctor who has completed the course of study required for an undergraduate degree, four years of medical school, and perhaps a lengthy residency program only to find that his application for staff privileges at a particular hospital has been denied. His frustration is compounded upon learning

\begin{footnotes}
\item[156] FLA. STAT. § 768.40 (1981).
\item[157] \textit{Auld}, 418 So.2d at 1022.
\item[158] \textit{Id.} at 1028.
\item[159] \textit{Id.} at 1026.
\item[161] W. VA. CODE § 30-3C-3 (Supp. 1983).
\item[162] \textit{Id.}
\item[163] \textit{Id.} The statute also does not protect reports of committee meetings from further review by another review organization or from judicial review of the findings of the review committee.
\end{footnotes}
that he is not permitted access to the review committee reports; nor is he allowed to depose those in attendance at the meeting to prove his allegations of defamation.

On the other hand, the quality of medical care is of utmost importance, and those charged with the duty of approving medical personnel for staff privileges need the reassurance that they can pursue that task utilizing methods best designed to promote forthright and candid evaluations. Those who have knowledge of a candidate's lack of credentials or poor performance may temper their remarks out of fear that they may suffer repercussions from the candidate who has access to the committee reports. The result may be that an unqualified doctor will receive staff privileges and proceed to harm or fatally injure a member of the unsuspecting public.

While the need for the free flow of information at peer review committee meetings would seem to justify protecting the records of such committees, preventing access by an applicant who has sued the committee does not seem consistent with statutes that accord qualified immunity to such committees. Because statutes have traditionally provided qualified, rather than absolute immunity, good faith will be an issue in a lawsuit. It would seem anomalous for the legislature to make good faith an issue and then deny the plaintiff the means to negate its presence.

In the case of IRB review, it is primarily the research protocol that is being evaluated, rather than the qualifications of the investigator. There does not appear to be as strong a need to protect the records because a board member may be less fearful that he will antagonize a colleague by pointing out risks inherent in research methods than he would by directly criticizing the qualifications of the colleague.

An IRB member could also assert the defense of truth in a defamation action. Truth has almost always been recognized as a defense to defamation in the United States, although some states require by statute that the defendant have a good motive or a reasonable justification. The member will be held to a reasonable man standard regarding the "strength of his belief, the grounds that he has to support it, and the importance of conveying the information." The burden will be on the IRB member to prove the truth of the defamatory statements. The statements must be proved to be true in whole, and if the defamation charges the investigator with persistent misconduct, proving one incident of such misconduct will not suffice.

The IRB member may seek to mitigate damages by showing: 1) that he properly retracted the defamatory statement; 2) that the investigator's reputation was

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164 PROSSER, supra note 65, at 797.
165 Id. at 796.
166 Id. at 798.
167 Id.
already damaged; or 3) that the IRB member actually believed his statements to be true.\textsuperscript{168}

VI. PROTECTION AGAINST LIABILITY

In addition to those protections against liability created by statute, and the defenses available to IRB members in tort actions, there are other steps a member can take to assure adequate protection.

Although the member can purchase private insurance covering his negligence, members generally receive little or no compensation for their services as board members and may therefore be unwilling to expend personal funds to purchase insurance. A less burdensome alternative would be for the member to condition his service as an IRB member upon the institution's providing liability insurance. Because of the absence of suits against IRB members thus far, and because IRB members could possibly be made employees or agents of the institution for the purpose of including them in the hospital's group rate, the cost to the institution should not be unduly burdensome. If the institution does not believe that the likelihood of suits justifies the cost of insurance, the institution could contractually arrange to indemnify members for any expenses incurred in defending suits or satisfying judgments against them.

Institutions could also require investigators to waive their right to sue IRB members or witnesses who testify before the board, as a condition of employment. Although such a waiver may come within the definition of a contract of adhesion\textsuperscript{169} because the institution stands in a somewhat superior bargaining position, the public interest in promoting candid discussions at IRB meetings will probably prevail over any claims of unconscionability.

Although the regulations require an IRB to maintain a record of "the number of members voting for, against, and abstaining"\textsuperscript{170} in each action, the regulations do not require a record of how each member voted. Using the MBCA analogy once more, section 35 provides:

A director of a corporation who is present at a meeting of its board of directors at which action on any corporate matter is taken shall be presumed to have assented to the action taken unless his dissent shall be entered in the minutes of the meeting or unless he shall file his written dissent to such action with the secretary of the meeting before the adjournment thereof or shall forward such dissent by registered mail to the secretary of the corporation immediately after the adjourn-

\textsuperscript{168} Id. at 799-801.

\textsuperscript{169} The "[d]istinctive feature of [an] adhesion contract is that [the] weaker party has no realistic choice as to its terms." \textit{Black's Law Dictionary} 38 (5th ed. 1979).

\textsuperscript{170} 45 C.F.R. § 46.115(a)(2) (1983).
ment of the meeting. Such right to dissent shall not apply to a director who voted in favor of such action.\textsuperscript{171}

An IRB member would be wise to urge the board of which he is a member to adopt a procedure for recording dissenting votes so that he would have proof of his dissent if it should become an issue.

VII. Conclusion and Recommendations

This Note has examined a few of the many instances of potential liability to which an IRB member exposes himself in the course of discharging his duties. The regulations governing research involving fetuses, pregnant women, in vitro fertilization, prisoners and children require even stricter scrutiny by an IRB and represent a corresponding increase in the potential for liability. While the task of an IRB member appears awesome from this perspective, and the potential for liability threatening, the defenses available to the IRB member and the legislatively created protections warrant a somewhat brighter outlook. In addition to the legislatively created protections such as qualified immunity, a court will apply common law concepts such as the reasonable man standard, absence of malice, lack of proximate cause, and overriding public interest where the IRB member's behavior has appropriately triggered their use.

However, for even the most scrupulous IRB member, the possibility of being sued will continue to be a very real and ever present threat. At a minimum, the IRB member may dread the embarrassment and time that a lawsuit would entail. Except for performing his duties with the due care that the law requires, the IRB member has little control over those aspects of his anxiety. Further, the member may have an even greater fear of financial liability. It is in this area that the IRB member has the means to reduce his uneasiness. The member can condition his continued participation as an IRB member upon the institution either providing him with liability insurance or contractually arranging to indemnify him for any expenses that arise out of a lawsuit.

The member can also encourage the institution to provide the funding necessary to adequately staff the IRB so that it may effectively perform all of the requirements imposed by the HHS regulations. This could include compensating IRB members for their services. This would serve to encourage them to devote more than the minimum hours they might otherwise be willing to expend fulfilling their roles as board members.

Those IRB members not presently protected by a statute providing immunity based on their status as agents of the state should encourage the legislators in their respective states to consider enacting such protective statutes. In those states with

\textsuperscript{171} Model Business Corp. Act § 35 (1980).
a current statute that provides similar immunity for members of a health review organization, IRB members should press for express inclusion under that statute's coverage. Because the statutes would only accord qualified immunity to IRB members, the threat of suit would still exist, but the member could feel secure that he would not be held liable for errors in judgment where the decisions were made in good faith. While there is always a possibility that any grant of immunity will allow some abuses to go undetected, it seems preferable in the long run to promote the goal of encouraging qualified individuals to serve as IRB members. Without such participation, the ultimate goal of protecting human subjects from the risks of research may never be realized.

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