Baby Fae and the Media: How the Law Allows Appropriate Access

by Nicholas Christakis and Morris Panner

On October 26, 1984, Baby Fae received a transplanted baboon heart to replace her own severely defective one. The IRB at Loma Linda University Medical Center in California approved this experimental procedure. In the aftermath of the operation, all involved, including the IRB and its members, were subjected to such intense media coverage that Dr. Richard Sheldon, the chairman of the Loma Linda IRB, ultimately argued that IRB membership "should be semi-anonymous; that is, known to the officials of the Office of Protection from Research Risks and the home institution, but off limits to the press."[1,p.11]

Dr. Sheldon's experience with the Baby Fae case prompted him to state that IRBs, though primarily constituted to protect subjects of research, also function to protect "persons, institutions, documents, and abstract ideas."[2] Specifically, Dr. Sheldon questions the propriety of having the review process open to the media. He argued:

> The whole IRB deliberative process is too valuable to be hauled into the circus-like atmosphere of the press conference. IRB chairmen should rarely, if ever, be seen on television. Even more disconcerting is to have television cameras actually come into the IRB council. This travesty renders deliberate and careful consideration impossible.
>
> The majority of what IRBs do is dull, boring and hard work. When the issues are controversial, the discussion becomes as heated and stressful as if it were a touchy family matter. Board members' protection must be assured.[1,p.12]

Dr. Sheldon is not alone in his frustration with press coverage of IRB meetings. At a recent conference on artificial organ transplantation, Dr. William DeVries recounted—with some annoyance—how, as the University of Utah IRB was considering his total artificial heart protocol, the journalists at the meeting turned to photograph each member as he or she voted.[3] He questioned whether such coverage is in the best interests of the patient.

Most IRB meetings neither warrant nor receive the media attention devoted to the Loma Linda or Utah IRBs. Nevertheless, both cases point to a new challenge for IRB members: dealing with the media. IRB members will confront the conflict between media interest and the benefits of a confidential review. Such extraordinary cases raise an additional challenge. IRBs ordinarily review two principal documents—the research protocol and the informed consent document. In cases such as that of Baby Fae, however, the IRB also reviews confidential information about a specific patient. The review of this information raises an unusual but important problem: the IRB must be careful to avoid becoming a vehicle for the violation of patient privacy.

Especially when considering dramatic procedures such as xenografts, IRB members may be obliged to explain the ethical and scientific reasoning behind their decisions to the public. The Baby Fae case, according to Richard McCormick of the Kennedy Institute of Ethics, exemplifies this point. He argues for full disclosure, including tapes of the IRB meetings at Loma Linda. "What human beings feel entitled to do to other human beings is a matter of grave public concern," McCormick argues. "A good test of one's appreciation of this is the willingness to endure and survive public scrutiny."[4,p.12] Ethics, McCormick insists, "is a public enterprise."

Members of IRBs and others argue for closed meetings by pointing out "that the assembled members of the committee—feeling that they are speaking in confidence—are likely to be appropriately critical."[5,p.4.36] And anyone who has served on an IRB can readily appreciate Dr. Sheldon's concerns about media scrutiny hampering IRB effectiveness. Yet, the proposed alternative of anonymity of IRB members and secrecy of meetings seems to be impractical—if not illegal, at least in some states. The issue, therefore, as Carol Levine has put it in the *Hastings Center Report*, is whether "the ethical review of research is a public concern or one best managed in the confines of medical confidentiality."[6] More specifically, to what extent should, and must, IRB deliberations and documents be open to the media?

The Law and Media Access

Federal law has no specific provision defining media access to IRBs. The DHHS regulations do not specify the level of disclosure of IRB documents except to note the right of access of "authorized representatives of the Department at reasonable times and in a reasonable manner."[7] Moreover, although the federal Freedom of Information Act (FOIA) allows access to government "agencies,"[8] IRBs would probably not fall under this category since data "generated by a privately controlled organization which has received federal grants, but which data has not at any time been obtained by the agency, are not 'agency records' under the FOIA."[9] If, however, the DHHS had obtained IRB documents, then the documents might be subject to FOIA control.

Still, there are potentially relevant state laws for IRBs, such as the open-government, or so-called "sunshine," laws. For state institutions at least, John Roberston of the University of Texas Law School argues that these laws "may require public access to IRB meetings since IRBs may be considered public or governmental bodies as defined by these statutes. They are created by and function as instrumentalities of public institutions, such as state universities and hospitals, to which open meeting laws clearly apply."[10,p.539] Robertson goes on to argue that the California statutes in particular, however, "appear" to exclude IRBs. In fact, these rules have not been subjected to any substantial litigation with respect to IRBs and the interpretation of the court could vary from jurisdiction to jurisdiction. Given this, IRB members can reasonably expect the sunshine laws to be applied to their meetings in certain situations.

William Ziprick, the attorney for Loma Linda, argued that California open government laws did not apply to Loma Linda since it is a private institution.[11] Thus, without any controlling state law, Loma Linda was free to make its own policy. He explained that the hospital keeps IRB deliberations confidential so the Baby Fae documents were not released to the press for public consideration.

Nicholas Christakis *is a second-year medical student at Harvard Medical School and a member of its Human Studies Committee.* **Morris Panner** *is a first-year law student at Harvard Law School and a former reporter for the* Miami Herald.

Frank discussion of IRB proceedings in the press, however, can be seen in light of sociologist Dorothy Nelkin's call on both journalists and scientists to produce a much more instructive and comprehensive type of reporting. The public, she points out, reads

> polarized images—of progress or peril, of hope or fear. New medical feats are duly reported but seldom the values that guide discussions about costly and controversial procedures . . . .
>
> . . . To understand modern scientific medicine, readers need to know its context: the political and economic bases of decisions, the social and ethical implications of research, and the limits as well as the power of science and technology as applied to the problems of health.[12,pp.544–546]

Nelkin takes particular note of the paucity of public information about the structure and function of IRBs.[13]

Media scrutiny of IRBs, in addition to any benefit, may also be harmful to the public. Premature disclosure of research protocols, made possible through the presence of the media at IRB meetings, might lead to news that is misleading rather than informative. For example, the press might choose to focus on an investigator's optimistic statements about the chances of success of a given treatment modality and overlook "whatever caution may be contained in the wording of the research protocol" itself.[14] This kind of sensationalism may ultimately work to the public's disadvantage. For this reason, many maintain that the public should learn of biomedical developments only after they have been reviewed in the scientific press. Alexander M. Capron, of the University of Southern California Law School, argues that "this method not only preserves the dignity of all involved—from scientists to patients—but also means that the public learns about genuine 'advances' rather than merely being titillated by bizarre cases of as-yet unproven import."[15]

In many ways, the aggressive character of the American press is antithetical to the thoughtful analysis requisite for scientific (and bioethical) decisions. Speaking of the Baby Fae case, Keith Reemtsma, a transplant surgeon at Columbia University, argues:

> Science and news are, in a sense, asymmetrical and sometimes antagonistic. News emphasizes the uniqueness, the immediacy, the human interest in a case such as this. Science emphasizes verification, controls, comparisons, and patterns. Such scientific studies may not be possible in time for the afternoon press conference, and the uncertainties that scientists express may be misinterpreted as a lack of candor.[16,p.10]

The press will, by its very nature, tend to focus on the particular aspects of a story that are sensational. Uncontrolled media access might thus lead to a type of reporting detrimental to the interests of the public in general and the patient in particular, rather than to the instructive coverage envisioned by Nelkin.

Limits to the Right of Access

But even under the most sweeping open-government laws, the media would not have an absolute right of access to IRB meetings and documents. Access is under significant legal control. The courts would consider at least three areas of restriction of disclosure: (1) doctor-patient confidentiality; (2) a researcher's proprietary interest; and (3) confidential statements regarding disciplinary and personnel matters. With respect to the FOIA, there is a further potential area of restriction: research studies, especially randomized clinical trials, are exempted from FOIA control in situations where premature disclosure of the data could compromise the conduct of the research.[17] If an IRB chairman or researcher could demonstrate that any of these interests would be jeopardized by full disclosure, the courts would prohibit access to the information.[18]

What this probably means in practical terms is that meetings could be closed when: (1) specific patients are discussed and confidential health or personal information is revealed; (2) potentially patentable products or techniques are discussed; or (3) potentially damaging statements are made in confidence about the abilities of a given investigator. Though these are broad categories, there is still much that would *not* be protected from disclosure, for example, a general discussion of the ethical and scientific basis of a protocol. IRBs devote many months of study to a protocol such as that involving Baby Fae even before the patient is known. If Loma Linda were a public institution, media access could not ordinarily have been limited until the IRB began to discuss a specific patient.

In the Baby Fae case, where one particular patient became the focus of the review, the most important reason to limit media access was concern about patient privacy. IRB meetings should not become a forum for the violation of patient rights to a confidential doctor-patient relationship. In this case, there were legal considerations as well. Ziprick explained that even if someone had challenged the Loma Linda Medical Center standing rule on the confidentiality of IRB meetings, concerns about Baby Fae's privacy would have allowed the hospital to withhold the information. The consent form signed by Baby Fae's parents prohibits the release of any information about the patient without their consent.[19] The California Confidentiality of Medical Information Act prevents a hospital or physician from acting against the wishes of the patient or releasing information that might identify him.[20] Similar laws in other states would allow an IRB to refuse access to information because it would compromise the rights of a patient.[21]

In sum, the timing of media scrutiny and the material examined are of critical importance both with respect to IRB function and patient confidentiality. If media interest is taken as a given, IRB chairmen and members must focus on making the difficult decision of what material truly deserves to be privileged in light of the legal standards. Willingly or not, IRB members may, on occasion, be cast in the role of "managers of biomedical news." Although from the vantage of IRB function this may—to some—seem to be a deplorable development, the media can in many situations establish access to IRB meetings and documents.

In the unusual cases where a specific patient is considered, the IRB meetings should be entirely closed, as allowed by law. Nevertheless, even in these cases the public need for general information should be met. IRBs should have a policy for dealing with the media. This makes legal and political sense. Lawyers, journalists, and IRB members have an important responsibility to establish responsible standards and methods for managing access to IRB discussions and documents. We believe, and interpret present laws to allow, that the media should have access to: (1) the scientific protocol; (2) the unsigned informed consent document; and (3) perhaps a one-page statement of the pros and cons guiding the IRB decision. This information should be released for public consumption.

The case of Baby Fae thus brings to the fore the inherent conflict between the workings of the media and the IRB's need to protect both the patient's privacy and the patient's right to a thorough and confidential review. At present, state open-government laws may allow access to IRBs. Sheldon and

others argue that this access works against the federally mandated function of IRBs (that is, candid ethical review). We believe that the legal guidelines provide sufficient protection both of the IRB review process and of the patient. We also believe that the general considerations behind protocol decisions are rightly open to the media. Open discussion of protocols and informed consent documents, when it does not endanger other specific rights, will build public confidence in the ethical review of research. Once a specific patient has been chosen for the procedure, however, that person's right to privacy must be carefully guarded.

ACKNOWLEDGMENT

We gratefully acknowledge the comments of Alan Brandt, Ph.D., on earlier versions of this article.

REFERENCES

[1]Sheldon, R.; The IRB's responsibility to itself, *Hastings Center Report* 15(No.1):11-12, February 1985.

[2]Sheldon, R., *op. cit.*, p. 11. For further consideration of this point in the similar case of an IRB considering a total artificial heart implant see also the following articles in *After Barney Clark*, M.W. Shaw, ed., Austin: University of Texas Press, 1984: After Barney Clark: Reflections of a reporter on unresolved issues by L.K. Altman, pp. 113-128, in particular p. 121; A spontaneous reply to Dr. Lawrence Altman, by C.N. Peterson, pp. 129-138, in particular p. 134; and Deliberations of the Utah Institutional Review Board concerning the artificial heart by J.A. Bosso, pp. 139-145, esp. p. 143.

[3]For more details, see F.R. Woolley, Ethical issues in the implantation of the total artificial heart, *New England Journal of Medicine* 310:292-296. 1984. Woolley was on the Utah IRB.

[4]McCormick, R.A.; Was there any real hope for Baby Fae? *Hastings Center Report* 15(No.1):12-13, February 1985.

[5]Levine, R.J.; The Institutional Review Board, pp. 4.1 to 4.73 in the Appendix to *Institutional Review Boards: Report and Recommendations* by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, DHEW publication No. (OS) 78-0009, Washington, D.C., 1978. This article contains a good review of some of the pros and cons of having open meetings; Levine seems to favor open meetings in most instances.

[6]Levine, C.; The subject is Baby Fae, *Hastings Center Report* 15(No.1):8, February 1985.

[7]DHHS Protection of Human Subjects, 45 C.F.R. §46.115 (1985).

[8]Freedom of Information Act 5 U.S.C. §552 (1984).

[9]*Forsham v. Harris* 445 U.S. 169 (1980).

[10]Robertson, J.; The law of Institutional Review Boards, *UCLA Law Review* 26:484-549, 1979. See also California Government Code §6252.

[11]William Ziprick (personal communication), November 15, 1985.

[12]Nelkin, D.; Managing biomedical news, *Social Research* 52:625-646, 1985.

[13]See Nelkin. *op. cit.*, p. 631. See also Altman, *op. cit*, pp. 121-122. Altman claims that the University of Utah created its own problems by not having IRB members discuss the progress of its deliberations publicly.

[14]Levine, *op. cit.* p. 4.37. See also Nelkin, *op. cit.*, p. 625, for an example of misleading premature disclosure.

[15]Capron. A.M.; When well-meaning science goes too far *Hastings Center Report* 15 (No.1):8-9, February 1985. For an argument from another perspective on the obligation of the scientific press to ensure accuracy of scientific information through peer review, see A.S. Relman, The Inglefinger Rule, *New England Journal of Medicine* 305:824-826. 1981.

[16]Reemtsma, K. Clinical urgency and media scrutiny, *Hastings Center Report* 15(No.1):10-11, February 1985.

[17]Ethics Advisory Board, DHHS; The Report of NIH for a Limited Exemption from the Freedom of Information Act, Report submitted to the Honorable Patricia Roberts Harris, Secretary of DHHS, May 21, 1980 (no. 81-9973). See also Gordon R.S., Jr.: Three current issues: The design and conduct of randomized clinical trials, *IRB: A Review of Human Subjects Research* 7 (No.1):1-4, January/February 1985, for further analysis of this point.

[18]Note that in addition to the exclusions discussed here for state open-government laws, there are several other exceptions to these laws and to the FOIA *not* relevant to IRBs (e.g., in the case of the FOIA, national defense secrets, the identities of federal agents or confidential sources of law enforcement agencies, information used by agencies supervising financial institutions, etc.): see FOIA, U.S.C. §552(b). See Robertson, *op. cit.*, pp. 537-543, for a complete treatment of the legal issues surrounding IRBs and public access.

[19]See Dommel, F.W. Report of the NIH site visit to Loma Linda University Medical Center, released by the Office for Protection from Research Risks on March 5. 1985; the informed consent form is reprinted in this issue.

[20]Confidentiality of Medical Information Act, California Civil Code §56.

[21]For further examination of this point in related situations, see Holder, A.R., When researchers are served subpoenas, *IRB: A Review of Human Subjects: Research* 7(No.4):5-7, July/August 1985, and also, Reatig, N., Confidentiality certificates: A measure of privacy protection, *IRB: A Review of Human Subjects: Research* 1(No.3):1-4, May 1979.

7

BEYOND LOCALISM:

A Proposal for a National Research Review Board

by Carol Levine and Arthur L. Caplan

In 1978 the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research said it best: when it comes to reviewing the ethics of research, a local committee is the place to be:

> [T]he rights of subjects should be protected by local review committees operating pursuant to Federal regulations and located in institutions where research involving human subjects is conducted. Compared to the possible alternatives of a regional or national review process, local committees have the advantage of greater familiarity with the actual conditions surrounding the conduct of research. Such committees can work closely with investigators to assure that the rights and welfare of human subjects are protected and, at the same time that the application of policies is fair to the investigators. They can contribute to the education of the research community and the public regarding the ethical conduct of research. The committees can become resource centers for information concerning ethical standards and Federal requirements and can communicate with Federal officials and other local committees about matters of common concern.[1]

But the National Commission also recognized that there are exceptions to this general rule. Acknowledging the controversy surrounding research on the fetus, it recommended that a National Ethical Review Body review certain classes of activities related to that category of research. The current federal regulations continue this policy:

> One or more Ethical Advisory Boards shall be established by the Secretary [of Health and Human Services]. Members of these board(s) shall be so selected that the board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. . .[2]

The regulations further state that the Board may establish certain classes of applications or proposals that must be submitted to the EAB, or need not be submitted. One class that is specifically

Carol Levine *is editor of the* Hastings Center Report *and managing editor of* IRB: A Review of Human Subjects Research. **Arthur L. Caplan** *is associate director of The Hastings Center.*