

Who Decides? The Composition of Institutional Review Boards (IRBs)

By Carl P. Forsberg

Abstract

Institutional Review Boards (IRBs)—committees responsible for the protection of human subjects in medical and social science research—are coming under increasing criticism. Researchers find them to be a hindrance to their work, while non-scientists complain that IRBs provide inadequate protection. Meaningful reform of the system for protecting human subjects requires a complete understanding of the contemporary form and function of IRBs. To that end, this study provides a more complete understanding of the composition, workload, and work habits of IRBs. Data were gathered from a stratified random sample of IRBs drawn from a list of the 892 IRBs registered with the Office for Human Research Protections (OHRP) as of February 2001. The IRBs were contacted by telephone and 87 of the sample of 89 chose to participate in the survey (a response rate of 98%). The survey revealed a number of problems with the current organization of IRBs including an overrepresentation of whites, researchers, and those affiliated with the concerned institution, and a lack of staff support for the increasingly heavy workloads of IRBs. These problems suggest two avenues of response to current criticism of IRBs:

- 1) increase the range of voices represented on IRBs to better comply with existing federal regulations and to provide more complete protection, and
- 2) lighten the burden of IRBs by increasing staff support, removing some of the roadblocks that frustrate researchers.

Introduction

We Americans have a certain ambivalence about scientific research: we have tremendous faith in science but we are wary of scientists and what they might do to satisfy their own curiosity and interests. In the past few years tragedies involving the death of research subjects at prestigious institutions have increased public concern about the conduct of science. It was a creeping suspicion of scientists that led to the creation—some three decades ago—of federal rules for the protection of individuals who are the subjects of research. These rules—Federal regulations 45 CFR 46, known as the “Common Rule”—stipulate that all federally-funded research involving human subjects be reviewed by a local committee known as an “Institutional Review Board” (IRB). IRBs are made up of volunteer members, recruited from the research institution and from the local community. IRBs meet regularly to review research protocols with the goal of insuring sufficient protection for research subjects: Are the subjects sufficiently informed? Does the researcher have a conflict of interest? Are there other, less risky, ways to conduct the investigation? Although originally aimed at reviewing just federally-funded research, IRBs have come to assume a much broader role; most institutions now require that all research involving human subjects, regardless of funding source, be reviewed by an IRB. The IRB system has been criticized lately for not adequately fulfilling the duties specified by the Common Rule.¹ Calls for reform of IRBs are often made with little or no evidence about the composition, workload, and work habits of IRBs. My study examines the

current form and function of IRBs providing the data needed to suggest ways of improving their performance.

Background

IRBs were created in response to a number of research abuses that came to the attention of the public in the 1960's.² In its current form the IRB system is highly decentralized and allows for great variation in IRB membership, policies, and operating procedures. IRBs are located in a large variety of institutional environments and differ widely from one another in the type of research they review and in their workloads.³

It is estimated that over 21 million people a year volunteer to be in a research experiment,⁴ and 3.5 billion dollars each year is invested by the federal government in research that involves human subjects.⁵ Most people involved with research would agree that IRBs have been instrumental in the protection of human subjects; these same people would admit the system is far from perfect.⁶ Criticism of the IRB system falls into two categories: In several places the system fails to provide adequate protection, and the system puts unnecessary roadblocks in the way of researchers.⁷ Reflecting on this situation, one bioethicist stated, "The system for protecting human subjects research is not simply sick—it is dead."⁸ This statement was made one day after Johns Hopkins, the leading recipient of government research money, was forced to halt nearly all its federally-funded research as a result of the death of a human subject. An investigation into the death at Johns Hopkins showed that the IRB system was to blame.⁹ Many believe that the suspension of clinical research at Johns Hopkins this past summer was a "symptom of a much deeper disease," indicative of a failing system, not just a failing institution.¹⁰

It is clear we need to know more about the membership and characteristics of IRBs. However, in the past decade there have been only two studies of these features of review boards. The most notable study, by Bell *et al.*, was published in 1998 and involved survey data from 404 institutions.³ A similar, less extensive study of university IRBs was published in 1995 by Hayes *et al.*¹¹ The findings of these two studies are summarized in Appendix C.

Methods

My study used a telephone questionnaire to survey 89 IRBs registered with the Office for Human Research Protections (OHRP). Questions were developed to focus on the purpose of the project. The survey was considered exempt from review by the research institution where this research was conducted. The survey was administered by telephone to ensure a high response rate. A sample population of IRBs representative of the distribution of IRBs in the United States was obtained by drawing a stratified random sample from a list of the 892 IRBs registered with the OHRP.¹² This list was current as of February 9, 2001. Contact information was generated for each selected IRB using the Internet, telephone listings, and personal contacts. Data from the surveys were coded and analyzed using the statistical analysis package SPSS. When needed, respondents were recalled to clarify answers.

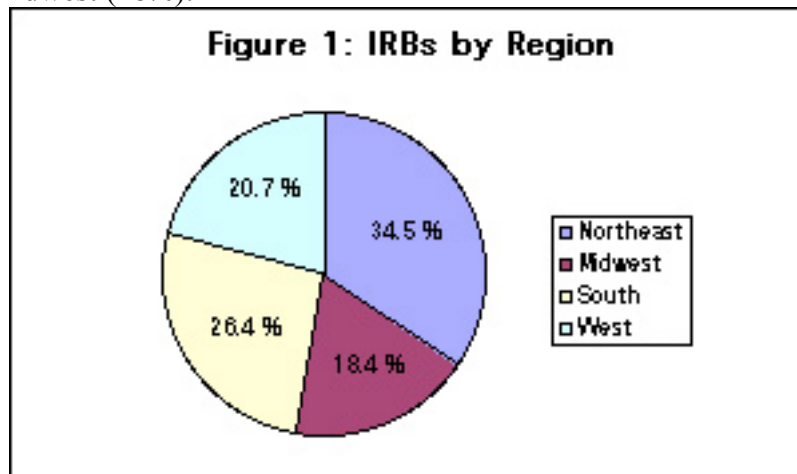
Results¹⁵

Eighty-seven IRBs counting a total of 1161 members participated in my survey (a response rate of 98%). As seen in Table 1, mean review board size was 13 members, with boards ranging in size from as small as five members to as large as 40. Using census definitions,¹⁴

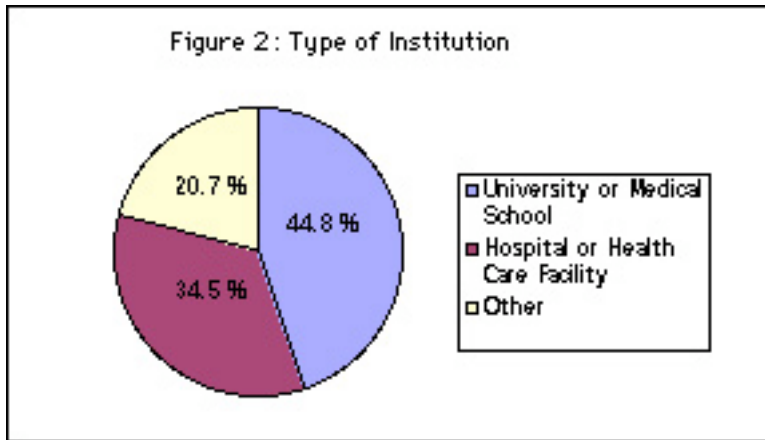
Table 1: IRB Size

	Members per IRB
Mean	13
Median	13
Mode	13
Std. Deviation	6
Minimum	5
Maximum	40

Figure 1 shows the geographic dispersion of IRBs: Northeast (35%), South (26%), West (21%), and Midwest (18%).



As shown in Figure 2, 45% of the IRBs were at a university or medical school, 35% were at a hospital or health care facility, and 21% were at another type of institution.¹⁵ At most institutions in the survey (62%), only one IRB existed, but some institutions in the study had as many as 20 IRBs.

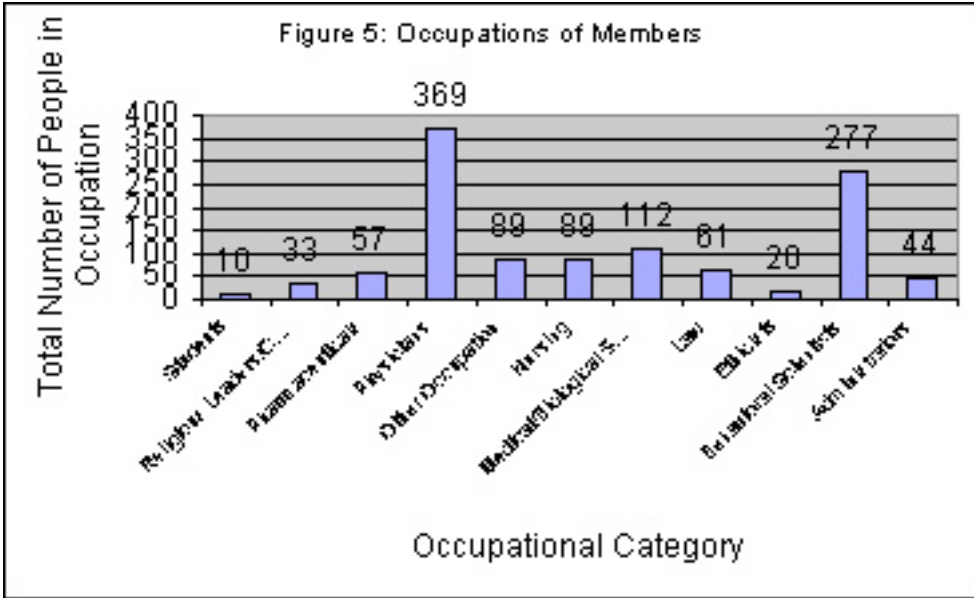
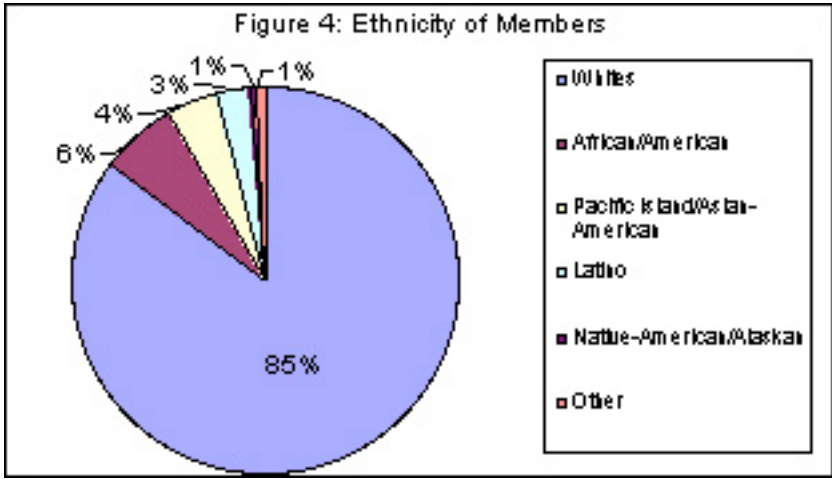
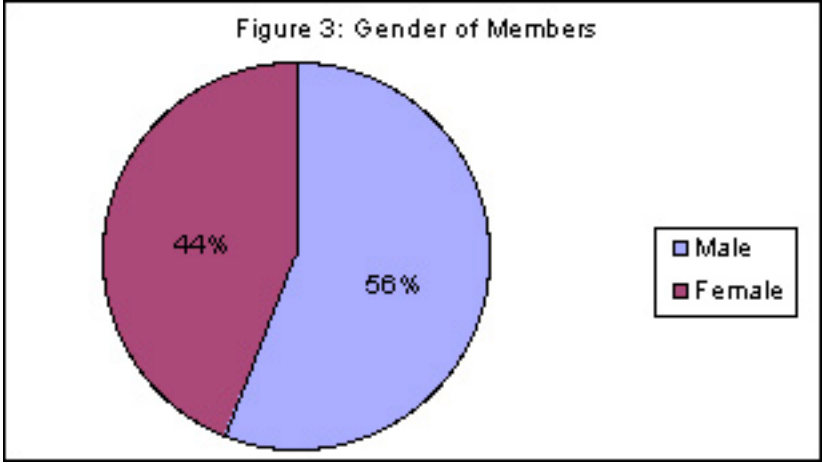


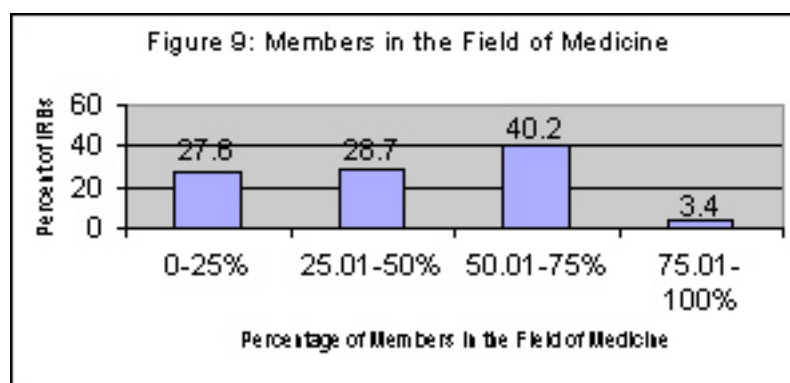
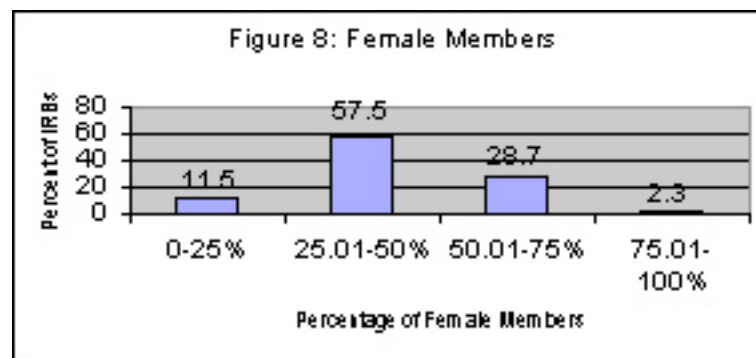
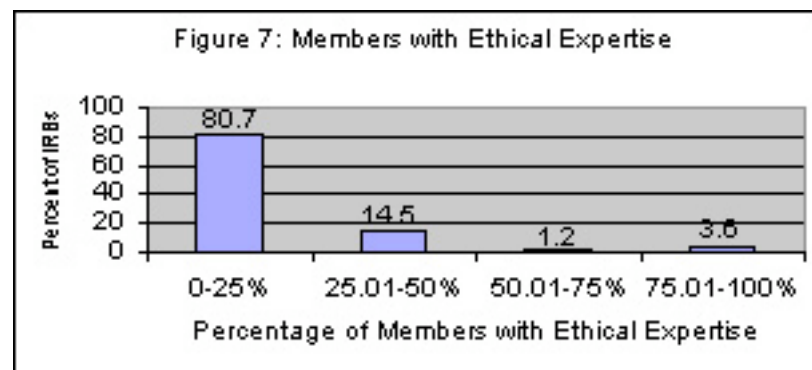
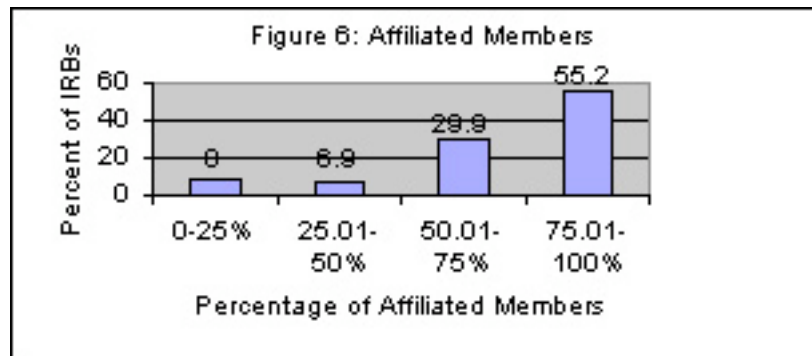
The mean number of paid Full Time Equivalents (FTEs)¹⁶ per IRB was two, with a range of 0-20. The mean number of current active human studies¹⁷ per IRB was 408, with a minimum of one and a maximum of 5000. An FTE on average managed 365 studies (Table 2).

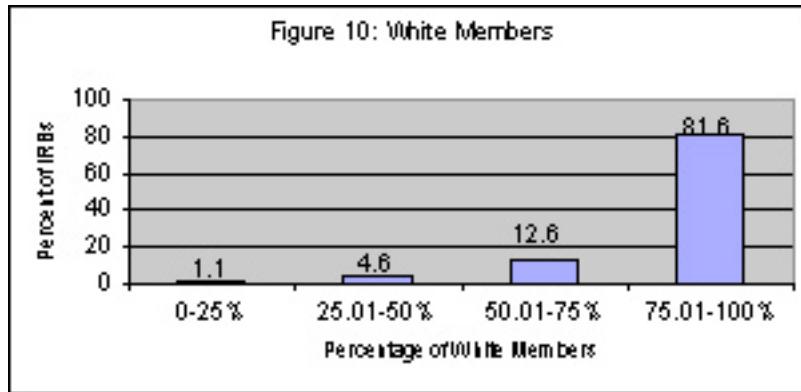
Table 2: General Information

		IRBs per Institution	FTEs per IRB	Current Active Studies per IRB	Current Active Studies per FTE
Mean		2	2	408	365
Median		1	1	181	200
Mode		1	1	100	200
Std. Deviation		1	2	769	841
Minimum		1	0	1	5
Maximum		20	20	5000	6750
Percentiles	25			59	67
	50			181	200
	75			525	348

Figures 3-10 show various characteristics of IRB members. Fifty-six percent of the 1161 members were male and 44% were female. Eighty-five percent of the 1161 members were white, with African/Americans making up the largest percentage of the remaining 15%. The occupational category with the greatest representation was that of a physician with 369 members (31%), while behavioral scientists made up the second most common category with 277 members (23%).







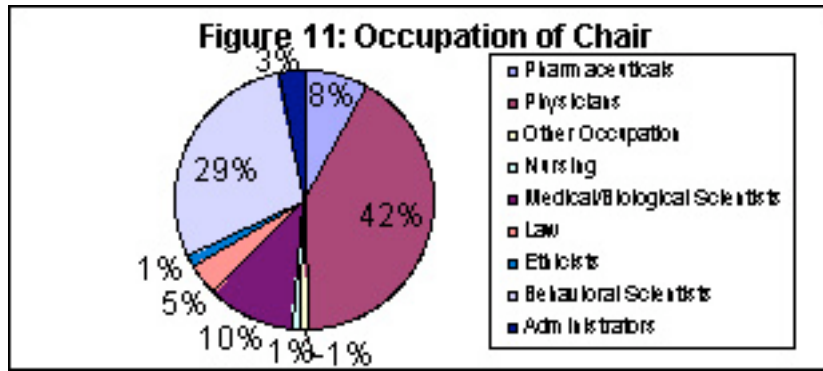
Members affiliated with the institution¹⁸ accounted for more than half of the members on approximately 86% of the boards. Members with special ethical expertise¹⁹ made up less than 25% of the membership on approximately 81% of the boards and less than 50% of the membership on 95% of the boards. Females were the minority on nearly 70% of the boards and made up less than 25% of the members on 12% of the boards. When physicians, medical/biological scientists, and people involved with pharmaceuticals were grouped into one category (Members in the Field of Medicine), they were found to make up more than the majority of members on approximately 44% of the boards. White members accounted for more than three-fourths of the membership on nearly 82% of the boards. Twenty-eight percent of IRBs had all white members.

The characteristics of the IRB chairs are shown in Table 3. Seventy-nine percent of the chairs were male and 89% were affiliated with the institution, with whites accounting for more than 94% of the chairs. Only 40% of the chairs had special ethical expertise and the most common occupation for a chair was that of a physician (42%).

Table 3: Chair Characteristics

Characteristic	Percent
Male	79
Female	21
Affiliated	89
Non-Affiliated	12
White	94
Non-White	6
With Ethical Expertise	40
Without Ethical Expertise	60
Physician (Most Common Occupation)	41

The distribution of chairs in the different occupational categories can be seen Figure 11.

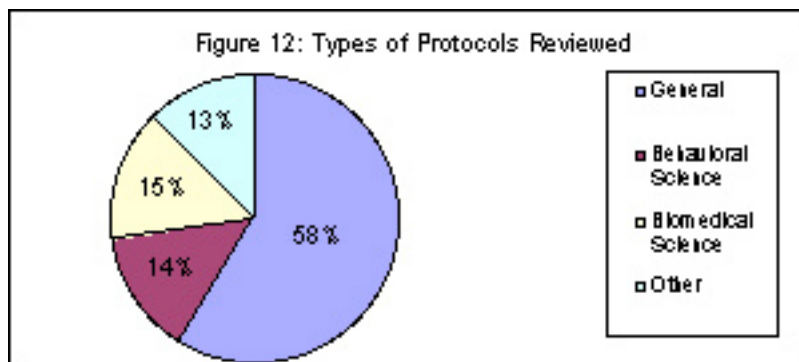


The work habits of the IRBs in the study are displayed in Table 4. Most boards met monthly and the average number of new proposals reviewed at each meeting was seven. The mean average length of each meeting was two hours.

Table 4: IRB Behavior

		Number of Times the IRB Meets in a Year	Number of New Proposals Reviewed at Each Meeting	Average Length of Each Meeting
Mean		14	7	2
Median		12	5	2
Mode		12	5	2
Std. Deviation		11	7	1
Minimum		1	0	1
Maximum		60	40	7
Percentiles	25	12	3	2
	50	12	5	2
	75	12	10	3

As seen in Figure 12, 58% of the boards reviewed general protocols.²² Boards that reviewed just biomedical science made up 15%, while boards that reviewed just behavioral science accounted for 14%, followed by 13% of the boards that reviewed other types of protocols.



The number of current active human studies were grouped into four intervals, shown in Figure 13. Approximately one quarter (23%) of the IRB offices²³ handled more studies than the other three quarters combined.

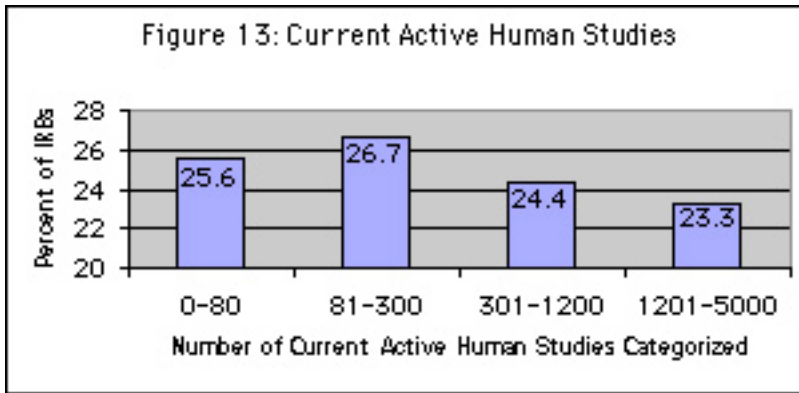
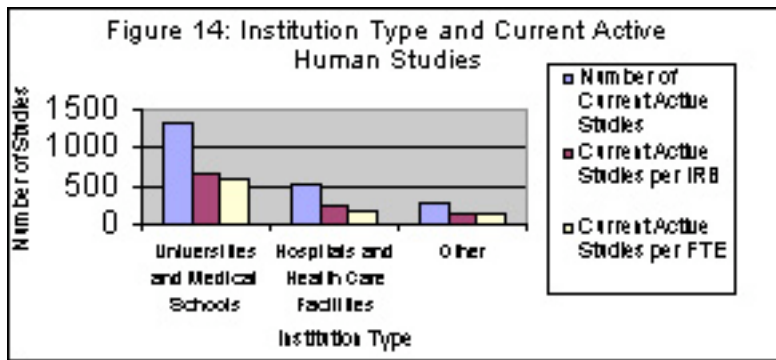
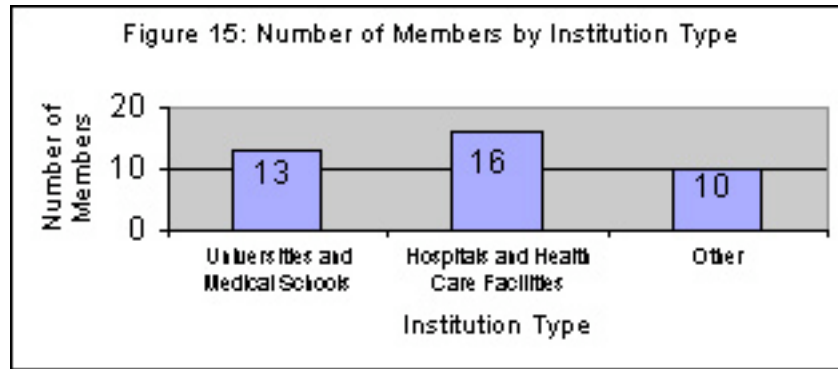


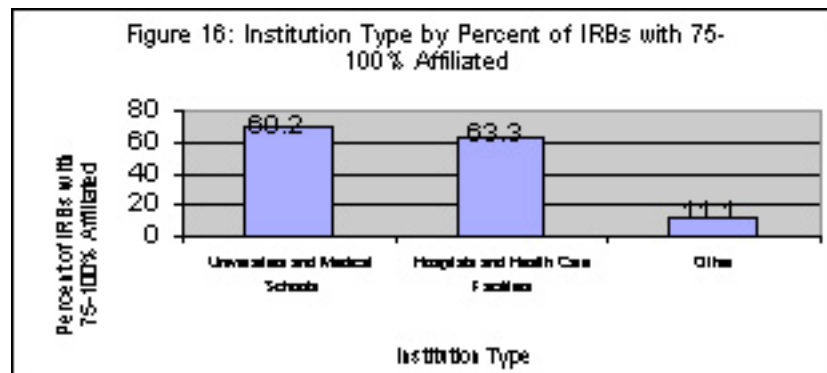
Figure 14 shows the type of institution compared with the number of current active human studies, the number of current active human studies per IRB, and the number of current active human studies per FTE. Universities and medical schools had more studies than hospital and health care facilities, and hospital and health care facilities had more studies than other types of institutions. These differences were found to be significant for the number of current active studies ($p=0.001$), for the number of current active human studies per IRB ($p=0.024$) and for the number of current active human studies per FTE ($p=0.077$).



Hospitals and health care facilities were found to have on average 16 members, while universities and medical schools had an average of 13 members, and other institutions had an average of 10 members (Figure 15). This relationship was found to be significant ($p=0.001$).



Also significant ($p=0.000$), was the fact that universities and medical schools, as well as hospitals and health care facilities had more than 75% affiliated members on 69% and 63% of their boards respectively, whereas other institutions had more than 75% affiliated members on only 11% of their boards (Figure 16).



Discussion

How well do IRBs follow the guidelines laid out by the Common Rule? The regulations state that “every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women...”²² In my study, no IRBs were found to be entirely male or female. The results in Figure 2 show only a slight disparity between the two genders with males making up 56% of the total members. This is *not* to say that all boards have a balance between genders. Figure 8 shows that nearly 70% of boards have less than 50% female members.

The Common Rule calls for diversity among the members.²³ Figure 10 shows that 82% of the IRBs had more than 75% white members. In fact, 28% of the boards were *all* white.

The Common Rule stipulates that “no IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest...”²⁴ Because affiliated members can sometimes place too much emphasis on the interests of the institution, conflicts of interest can arise if these members dominate an IRB.^{1,25} Over 85% of IRBs in this study have more than 50% affiliated members, creating a strong possibility for conflicts of interest.

In their recent report on human subjects protections, the National Bioethics Advisory Commission (NBAC) stipulated that nonscientists make up at least a quarter of an IRB's membership. NBAC also recommended that at least 25% of an IRB's members come from outside the institution.²⁶ If these recommendations were implemented, many IRBs in this study would not meet the standards.

The fact that 81% of the IRBs in the study reported less than 25% of their members as having special ethical expertise (as seen in Figure 7) is noteworthy. Also of interest is the fact that only 2% of the 1161 members were formally identified as an ethicist, and 77% of the boards had no members in this occupation. These facts may or may not constitute a problem per se, but it is clear that most IRBs do not have many members who are professionally trained in ethics. In fact, only one IRB reported 100% of its members as having special ethical expertise.

The OHRP investigation into the tragedy at Johns Hopkins this past summer concluded that many of the problems that were discovered “may be indicative of IRBs overburdened by the large volume of research for which it has oversight responsibility.”⁹ The results of my study suggest that this is an endemic problem. The mean number of FTEs per IRB was two. At some institutions, a single part-time person would be responsible for managing thousands of studies (Table 2). The data shown in Figure 13 show that some institutions have very few ongoing studies to oversee while others have an extraordinary amount. It appears from the data that the type of institution has something to do with this. Figure 14 shows the relationship between the type of institution and workload. From these data it can be seen that staff of IRBs at universities and medical schools have a heavier workload (when measured in terms of the number of current active human studies) than IRB staff located at hospitals and health care facilities and at other types of institutions.

Conclusion

The progress of medical and social science is contingent on public faith in science and the conduct of scientists. Recent research-related tragedies—at Johns Hopkins and elsewhere—have attenuated that faith. These very public failures of science are not the simple result of evil scientists, driven by greed or blind ambition; rather they are a product of structural problems in the system of review created to protect human subjects.

My research points to some of the more egregious problems in the current structure of IRBs. A close look at who decides the fate of volunteers in research shows that not all voices are represented. The membership of IRBs—with an overrepresentation of whites, researchers, and those affiliated with the concerned institution—suggests that the interests of the researchers and the research institution come before the interests of the subjects of research. Furthermore, the lack of staff support for the work of IRBs indicates that administrators at research institutions do not take the work of IRBs seriously.

Those who wish to change the system that protects the human subjects of research would do well to pay attention to the findings of my study. Two immediate changes are called for: first, the range of voices represented on IRBs should be increased to follow the

guidelines set forth by the Common Rule to their fullest extent; and second, more support must be given to IRBs in order to reduce the burden on the system.

This study also highlights the need for more research on the structure and function of IRBs. Future research should go in two directions. There should be a focus on a larger sample population of IRBs—perhaps all registered IRBs in the U.S.—to obtain a thorough description of the structure of IRBs, and several ethnographic studies should be undertaken in order to gain an understanding of how members of IRBs interact and make decisions. These two foci will provide the knowledge we need to truly protect those brave individuals who are willing to be subjected to science.

Acknowledgements

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16. All Tables and Figures referred to in the text are displayed in the Appendices. See Appendix A for tables and Appendix B for figures. Percentages may not equal 100% due to rounding error.
17. The region groupings were obtained from the U.S. Census Bureau. Available from: <http://www.census.org>.
18. Other types of institutions were defined as institutions that could not be grouped into the categories of universities and medical schools, or hospitals and health care facilities. An example would be a private research institute.
19. Full Time Equivalents were defined as the number of people working full time as paid support staff to the IRB.
20. The number of current active human studies figure represents the number of ongoing studies at the institution where the IRB was located. That number was divided by the number of IRBs at the institution to find the number of current active human studies per IRB.
21. Affiliated members are those members who are affiliated with the institution where the IRB is located.
22. The figure for the number of members with special ethical expertise was obtained by asking: "how many members are considered as having any special ethical expertise?" This was described to respondents as meaning the number of people on the board that had any professional training in ethics.
23. IRBs in the "general protocols" category were IRBs that reviewed both behavioral and biomedical protocols.
24. When more than one IRB existed at an institution, the figure for the number of current active human studies represents the number of studies for multiple IRBs at an institution. In this case, multiple IRBs would be run from an office at the institution that handled all human subjects research. Therefore, it is necessary to report this figure by IRB office.
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