

PREVENTIVE MEDICINE: SCIENTIFIC CONDUCT IN THIRD SECTOR RESEARCH

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INTRODUCTION

As the increasing number of submissions to the ISTR, ARNOVA, and other global conferences oriented to information sharing about third sector research suggests, there is a burgeoning interest in empirical and theoretical examinations of this sector and a corresponding growth in the level of research productivity. Studies range from large to small scale, empirical and theoretical, qualitative and quantitative, longitudinal and single point in time, historical and contemporary, single nation and cross-national, evaluative, descriptive, and exploratory. This very positive development in the production and transfer of knowledge related to the third sector, however, also comes with some risks. Given the commitment to increase the capacity and productivity, the subject of appropriate research conduct is germane to all those engaged in third sector research worldwide.

The United States, along with countries such as the United Kingdom, Germany, Australia, and South Africa, are investigating what has been termed the “big problem” of scientific misconduct (Altman, 1998). An accumulating number of cases publicized in news accounts around the world of alleged and substantiated scientific misconduct suggests that these are not isolated events in particular countries. The seriousness of the incidents exposed by the media point to the need to establish the common bases for these wrongdoings as they apply to third sector research and to identify strategies of preventive action. This paper examines instances of scientific misconduct which have occurred in recent years worldwide and explores their implications for the burgeoning research enterprise within the third sector. The specific area of concern is on research emanating from or addressing voluntary (third sector) health and human service organizations. However, the issues related to research conduct are pertinent to all third sector organizations.

Scientific misconduct or, more positively, appropriate conduct in the realm of research inquiry, is a topic that has received very little attention in the third sector literature. Although the majority of cases of scientific misconduct which have received international publicity are confined to the hard sciences, there are important implications to be derived for the growing research enterprise related to the third sector.

First, background is provided on the growing research enterprise in the third sector and some reasons that account for it. Next, some of the more prominent cases of substantiated scientific misconduct in the U.S. and globally during the time frame of 1995-2002 are identified and their common elements and unique features explored. The underlying problems that allowed these cases to occur and their implications regarding third sector research are then explored.

The salience of the issue of scientific conduct to third sector research relates to two primary factors: (1) the increasing demand from funding sources that voluntary agencies document that there are tangible outcomes to the work they perform, and (2) a growing desire among scholars, administrators, and practitioners to enhance the empirical knowledge base related to the functions, goals, and operating modes of this sector. The increasing production of third sector research intersects with the issue of appropriate research conduct in regard to legitimacy of method, the validity and accurate reporting of findings, and the protection of human subjects. Recommendations are offered in regard to the prevention and/or resolution of

potential or actual instances of scientific misconduct in third sector research.

TERMINOLOGY

Nations may use different terms to define the same or similar phenomenon. In the United States, NGOs are referred to as not-for-profit, nonprofit, or voluntary organizations, all generally referencing the same group of agencies. Scholars and researchers internationally refer to this grouping of organizations as the third sector or civil society (Katz, 1999). This sector constitutes a diverse group of formal organizations that are, according to Kramer (1998, p. 6), "self-governing and non-profit distributing, have some degree of voluntarism, and are expected to produce a public benefit". For purposes of this discussion, the third sector is the umbrella term used to describe the totality of nongovernmental agencies (NGOs). With greater specificity, reference is made to voluntary or nonprofit organizations, the nomenclature commonly used in the United States to describe charities.

Given the diversity of this third sector, discussions are best undertaken within similar groupings. The groups selected for this analysis are those concerned with the financing and delivery of health and human services. Human service organizations, the vehicle through which most health and human services are provided, are those which assist in the physical, emotional, and sometimes spiritual growth and development of individuals, families, groups, and communities (Gibelman, 1995). The services offered by these NGOs are, typically, "uniquely intimate and personal in nature" (Wellford & Gallagher, 1988, p. 49). Their focus of concern is the human condition, or human well-being. The term "research" refers broadly to the use of a variety of systematic procedures to seek facts or principles (Barker, 1999).

Individual nations have adopted different definitions of scientific misconduct, are in the process of considering such definitions, or have not yet begun to address the issue. For purposes of this discussion, the definition provided by the U.S. White House Office of Science and Technology Policy ("New Definition Proposed", 1999, p. 4) is used: "Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results". The definition is notable also in specifying what research misconduct is not: "honest error or honest differences of opinion" ("New Definition Proposed", 1999, p. 4).

Of interest is the sparse attention in the literature devoted to defining appropriate scientific conduct. One can assume that, in the absence of misconduct, research conduct has been appropriate. This assumption, however, belies the unknown universe of cases of misconduct that simply go undetected. Good scientific practice would also include attention to the protection of human subjects, valid science (in regard to the benefits to be derived from the research), methodological soundness, and honest reporting of findings.

METHODOLOGY

The media functions throughout the world as a forum of communication, with the press assuming the role of "filter" — selecting what is important for us to know and in how much detail. It is a fertile source of information to track and document events and stories. For purposes of this descriptive study, the search was limited to the print media. Two primary search engines were used to identify and obtain newspaper articles. First was Lexis-Nexis, a computer assisted

research service that includes a large data base of full-text news publications. The second search engine used was ProQuest, a comprehensive data base that includes newspapers, journals, periodicals, and newsletters. Although there was some duplication in using two comprehensive data bases, it was found that they identified some different articles or revealed articles that carried slightly different perspectives. A comprehensive search was conducted between January and June 2002 for the time frame of 1995-2002 for both U.S. and international stories about research misconduct.

The search was initiated using the key words "scientific misconduct" and a variety of variations (e.g., research conduct/misconduct; ethical research practice) were then attempted to see if they would yield additional articles. The search yielded hundreds of articles related to scientific conduct, the majority of which concerned allegations of misconduct or commentary about the state of affairs. In some cases, the print media's attention was world-wide and sustained over time, resulting in literally hundreds of articles about one situation.

The articles were analyzed by the use of qualitative content analysis, which is the method of choice for studying themes and language (Rubin & Babbie, 1997). Content analysis refers to any technique for making inferences by systematically and objectively identifying special characteristics of the message (Berg, 1995). Qualitative content analysis is well suited to "examining ideological mind sets, themes, topics, symbols, and similar phenomenon" (Berg, 1995, p. 176). Further, this methods permits patterns and themes to emerge from the data (Rubin & Babbie, 1997).

No efforts were made to quantify the number of cases, since it is a given that many cases of misconduct go undetected or are resolved at the institutional level without receiving publicity. The goal, rather, was to identify themes and issues related to scientific conduct and to draw implications for the burgeoning research in and of the third sector.

Study Limitations

There are several limitations associated with this methodology. One limitation is the inclusion of only one form of media. Another limitation is that the use of the internet as a search vehicle allows access to some, but not all of the world-wide press. The total universe of newspapers throughout the world is unknown and thus there is no claim made to any representation of the print media. Since the conduct of a search via the internet involves the use of key words, it is possible that some cases were omitted because they fell under different terminology and were thus not recognized.

Finally, the decision to limit the time span of the search to the most recent few years meant that information was generally lacking about the outcome of the allegations reported. As discussed below, such outcomes, particularly when they involve external investigations or legal proceedings, may take years. Thus, many cases were not included in the analyses because they have not moved from the stage of "allegation" to "substantiated".

Impetus for Developing Capacity

The production of research on the third sector is, no doubt, a reflection of the growth of this sector throughout the world and its increasing viability as a logical alternative to direct government provision of services. The status gains of the third sector have made it both desirable and necessary to engage in more far-ranging practice research. Such research production has also furthered the international exchange and transfer of the knowledge produced through empirical investigation. Although there has been a significant expansion in the production of research related to the third sector, as evidenced in professional and academic journals, the subject of research conduct, per se, is notable in its absence.

The impetus for third sector research comes from a variety of sources, both internal and external. Internally, administrators and practitioners seek to find out whether the services and interventions provided have any demonstrable impact on the consumers of service; to compare the cost of providing different services; or to explore the need for instituting a new service. There may also be a push – internally or externally – to explain certain social phenomenon, such as why teenagers engage in high-risk sexual behaviors even when they are aware of the potential consequences. This latter type of research may be of particular interest to academic researchers or public policy makers who are concerned with broader social behaviors and seek information for future policy and program initiatives.

Government, private foundations and managed care companies are demanding greater performance accountability (Martin, 2000). Third sector organizations, particularly those in the health and human services, are being called upon to document and demonstrate the quality and cost-effectiveness of the services they provide and to prove that these services are effective in changing the lives of people (Almgren, 2002; Cournoyer & Powers, 2002). These activities are frequently classified under the broad category of “accountability”.

Accountability

Accountability is defined broadly as “the extent to which an organization is answerable to its community, the consumers of service, and/or to governing bodies, such as a board of directors, for its processes and outcomes” (COA, 1997, p. 5).

Under the rubric of accountability is the process of continuous quality improvement. The Council on Accreditation (1997), a national voluntary accrediting body for human service organizations in the U.S. and Canada, defines quality improvement as an ongoing process in which the organization:

- C allocates appropriate resources, equipment, and personnel to accomplish the purposes stated in its mission;
- C has clearly defined policies and procedures to guide staff responsible for service provision; and
- C has a well defined plan for anticipating, correcting, and ameliorating problems.

Through such processes, human service organizations evaluate the effectiveness and efficiency of the services provided, determine whether these services meet pre-determined expectations about quality and outcomes; and, with this information, correct any deficiencies

identified (COA, 1997).

Outcome Measures

The use of outcome measures is increasingly popular within the human services, borrowing principles long used in for-profit enterprises. Funding sources have begun to tie reimbursements and future contracts to the ability of an organization to document that its programs and services have achieved their stated goals as measured, for example, in changed behavior among individuals and groups served in the desired direction. In this framework, efforts are being made in some agencies to include outcomes or results achieved, as measured by some pre-determined criteria, as part of the evaluation process. For example, how many children were returned from foster care to their biological parents? How many patients were discharged from the psychiatric hospital into a community half-way house? How many children received health screenings and inoculations?

Of particular concern to the third sector is the political context of social research. A growing proportion of third sector research seeks to assess and improve the conceptualization, planning, management, administration, effectiveness, and efficiency of health and human service programs toward the goal of enhancing the utility and outcomes of interventions (Rubin & Babbie, 1997). Many different methods may be applied to research that is goal-oriented; the resultant findings are intended for practical application. This form of research may be considered evaluative in nature, in that it seeks to determine outcomes or consequences of social interventions. The focus on outcomes in large part relates to the demand that programs in the public interest meet the test of cost-effectiveness. Client benefit is not the sole criteria. The client benefit is seen within the context of and measured against the cost of the service and the resources utilized to achieve and maintain the outcomes (Almgren, 2002). Thus, evaluation research is intertwined with growing demands for accountability.

The measurement of outcomes involves planning and implementing systematic evaluation processes. The information derived is a major source of input for the organization about target areas of change, as it helps to identify issues and problems, such as any discrepancies between service goals and the outcomes achieved. Outcome measures, then, can provide the essential information upon which organizational innovation and improvement can occur. The desire to gain knowledge by which to plan and improve the programs of service offered through the third sector is a strong motivating force to develop research capability. Such innovations span the gamut of organizational concerns — structure, finances, leadership, staff, inter-organizational relationships, programs, target populations, and services.

What Research is Being Conducted and by Whom?

A look at the ISTR conference program or, within the United States, that of ARNOVA, shows a panorama of the concerns, issues, and questions about which researchers and practitioners seek to increase our knowledge and understanding. The range of these contributions also suggests the growing methodological sophistication and diversity which now characterizes the study of the nonprofit sector (Clary, Gibelman, & Ostrander, 2001). Themes include:

- C Qualitative and quantitative approaches
- C Both large and small data sets

- C Historical and contemporary analyses
- C Experiences of the self; ethnographic case history
- C Longitudinal and single point in time designs
- C Surveys, interviews, and secondary data analyses
- C Case studies.

Empirical and theoretical examinations of phenomena collectively add to our understanding of the complexities of the nonprofit sector and the factors that account for changes in NGO status, help formulate new areas of inquiry and specific research questions, and suggest different applications of methods to the study of nonprofit institutions and practices. These various methodologies, when tested, provide guidelines for future duplicative or extended research and provide a framework to better design studies and construct theory to continue knowledge building (Clary, Gabelman, & Ostrander, 2001).

Voluntary health and human service organizations are concerned with improving the quality of life for individuals and groups and addressing the social maladies of society. This mandate involves a critical link between research, practice and policy. Practice-based research and evidence-based practice are two of the terms that have been used to describe the imperative for voluntary health and human service organizations to understand, use and contribute to research and policy (Mizrahi, 2002). The evidence-based movement is based on the recognition that health and human services interventions must be linked to demonstrated outcomes. To date, the successes of human service interventions have been largely anecdotal. The challenge is to empirically assess outcomes without trivializing the complexities of treatment (Vallianatos, 2000). Historically, there has been a pronounced lack of rigorous research to shed light on the most effective means to prevent or resolve human problems (Inouye, Ell, & Ewalt, 1994).

An unknown, but seemingly sizable proportion of third sector practice-oriented research is conducted under auspices other than that of a university. This suggests that research is carried out by practitioners less well versed in research conduct than university faculty who have expertise in research methods and ethics. The expansion of third sector research, therefore, is taking place in the absence of clear ethical or procedural guidelines, widely shared research standards, and systems of oversight. This is further complicated because the research is being conducted world-wide, across disciplines, and under a variety of organizational-types.

Within voluntary health and human service organizations, there is (or should be) special concern for the procedures used to enroll subjects. For informed consent to be meaningful, adherence to certain procedures are required. In general, these procedures concern the sharing of information about the purposes of the intervention, participation, or protocol, and the risks and benefits involved (Engelhardt, 1986; Beauchamp & Childress, 1994; Minogue, 1996). To provide informed consent, the participant/subject must be competent to understand the information and be free of intimidation or coercion so that the decision to participate is voluntary. Specific acknowledgment must be obtained about the voluntary agreement to participate and special scrutiny is needed for protocols involving children and at-risk or vulnerable populations (i.e., mentally ill, prisoners, pregnant women, etc.). By definition, many people served by health and human service organizations are vulnerable by virtue of their health, social or psychological status. This suggests the need for vigilance in the review of protocols.

When the research is under the auspices of a voluntary agency without connections to universities or other research centers, another concern arises: that of coercion. Clients of these agencies may fear that if they do not want to participate in the research – whether actively through completion of interviews or questionnaires, or passively, by allowing their case records to be reviewed – they may risk termination of services. The issue here is not the reality of penalties for non-participation, although there may be such instances, but the *perception* that there may be penalties.

The good news is that there are multiple stimuli for research production and an empirical approach to understanding and improving the quality of third sector programs and services. The bad news, however, lies with the lack of systematic standards or procedures to guide research. In this respect, an exploration of the issues of scientific misconduct sheds light on the potential pitfalls for researchers of the third sector.

THE EMERGENCE OF SCIENTIFIC CONDUCT AS A PROBLEM

Protection of Human Subjects

Early impetus for the development of standards of scientific conduct grew, not surprisingly, from evidence that misconduct was an issue. Concerns centered largely around the concept of informed consent and a growing acknowledgment of the need to protect patients from exploitation in their unequal relationships with physicians (Gibelman & Gelman, 2001). The Tuskegee Syphilis Study and the Milgram Obedience Experiment, among others, violated public sensibilities about involuntary exposure of people to harmful medical and scientific procedures without advisement about the true nature of the risks involved (Faden & Beauchamp, 1986).

Concern about protecting human subjects in research activities was recognized by the National Institutes of Health in 1966 with the issuance of policies for the protection of human subjects. By 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued its report, known as the Belmont Report (45 C.F. R. 46), mandating the establishment of institutional review boards (IRBs). Since 1985, federal law has required universities to develop and implement procedures for approving research protocols and investigating scientific misconduct (Ellis, 1999).

The definition of scientific conduct, let alone how to address it, remains contentious in the U.S. and elsewhere (Horton, 1995; Mads, 1996; Hargreaves, 2001). Should the definition be narrow or broad? The broad definition, currently in effect in the U.S., goes beyond misconduct as confined to fabrication, falsification, and plagiarism, and includes “other” serious deviations from accepted research practices. A problem with this definition, however, concerns the principle of due process. How are researchers to be held accountable if they do not know the proscribed activities and processes in advance (Nylenna, Anderson, Dahlquist, Sarvas, et. al., 1999)? Will we know misconduct when we see it, given the amorphous nature of “other”?

Another issue concerns the seriousness of the problem of misconduct. Commentators are of diverse opinions. Some see clinical fraud as common (Brainard, 2000c; Rippere, 1995), or on the increase (Mads, 1996), or perhaps not such a problem after all, but one which should be looked into (Horton, 1999). Commentators do, however, agree that the issue is one of trust –

among researchers, funders, editors who publish the findings, and the general public who rely on science to improve the human condition.

The mistakes of researchers in allied disciplines, discussed in the next section, suggest the scope and magnitude of potential areas of scientific misconduct that may similarly affect third sector research. Further, the record on misconduct shows that attention to the initial review of protocols is only a beginning step in an ongoing process necessary to ensure scientific integrity. Although a systematic process for reviewing research proposals, including attention to scientific validity of the study design, can alleviate many potential problems, it is in the reporting of research findings, at least to date, that the allegations of scientific misconduct are most likely to occur. Reports of research are, in fact, reviewed; how research is carried out and findings reported are subject to scrutiny, and, sometimes, reprisals. This fact presents a formidable challenge to the third sector in the development of an enhanced research capacity.

SCIENTIFIC MISCONDUCT: CASE EXAMPLES

Since the highest proportion of government funds, in the U.S. and elsewhere, has traditionally been allocated to bio-medical research, it is not surprising that this is the arena in which the majority of scientific misconduct allegations have surfaced. Table 1 provides a sampler of substantiated cases of scientific misconduct in the U.S. for the period 1995-2002. Table 2 provides a look at substantiated cases of misconduct world-wide for the same time period.

INSERT TABLE 1 ABOUT HERE

INSERT TABLE 2 ABOUT HERE

The majority of cases of misconduct concern the research process after the point of initial protocol review and approval. Researchers have been found to fabricate both the process and outcome of their research. Plagiarism – stealing the thoughts or words of another – has also been characteristic. Unearthing such misconduct occurs by happenstance, when and if the research is presented and/or published in peer reviewed journal, a route that researchers of the third sector also follow.

Several of the cases displayed in Tables 1 and 2 went undetected for years. For example, in Germany, two prominent molecular biologists were found to have fabricated data in 94 or more scientific papers which were published in leading international journals over a 10 year period (Bollag, 1998a; Koenig, 2001). A substantial number of the articles already reviewed or are on the agenda for future review listed four or more co-authors, raising the issue of the liability for wrongdoing of all authors, even if their role was honorary (Abbott, 1998; Steimle, 1998; Hagman, 2000; Weber, 2001). Continued investigation revealed far more extensive fraud (Hagman, 2000). Several years later, the chief of the medical center in which the misconduct occurred was also subjected to disciplinary proceedings and sanctions (Koenig, 2001). This case was the impetus for the Deutsche Forschungsgemeinschaft (DFG), Germany's main research

granting body, to appoint a commission to work out recommendations on professional self-regulation in science, a process which has spanned several years and remains “in process” despite deadlines.

In the Nordic countries, one criteria used to determine dishonesty is whether the deviation from good scientific practice is intentional or “accidental”(Nylenna, Anderson, Dahlquist, Sarvas, et. al., 1999). The U.S. makes no such distinction, although in the penalty phase, such matters are considered. The U.S. cases and the international cases show differential levels of punishment, apparently based on the seriousness of the misconduct.

Punishment/Sanctions

Most research review procedures occur at the protocol stage - that is, before the research takes place. However, a preponderance of misconduct has occurred in the reporting of findings. The majority of cases highlighted in Table 1, for example, were unearthed because the study and its findings were published in peer reviewed journals. This also explains the disproportionate number of cases involving alleged publication misconduct (White, 2002).

Although sanctions vary in proportion to the misdeed, there is no standard penalty in any country. Sanctions range from censure and firing to ineligibility for publicly-funded research grants and contracts. In China, Pan Aihua, who plagiarized an earlier paper authored by Canadian researchers, was removed from his position at Peking University, but went on to become general manager of a university-owned bio-technology company (Xiguang & Lei, 1996). In most instances, however, sanctioning is likely to be lethal to one’s research career.

With the exception of the U.S., sanctions for scientific misconduct were at the individual rather than institutional level. However, the degree of embarrassment for the sponsoring institution cannot be measured but is no doubt substantial. The concern for institutional reputation has been expressed by colleagues and administrators in several of the international cases. A notable example, with some irony, is again the case of Pan Aihua of China. Official spokespersons about this situation commented that it had damaged the country’s scientific reputation (Xiguang & Lei, 1996). Chinese officials took swift action, but were stymied by a lack of consensus about the best way to reduce or eliminate such unethical behavior. Ernst-Ludwig Winnacker, President of the DFG, the German research agency, has blasted what he sees as the light punishment given to researchers involved in major cases of scientific fraud (Schiermeier, 2002).

“Punishment” at the institutional level has been applied in recent years to several U.S. institutions, in effect halting all research (well beyond the specific area in which irregularities were found) sponsored through government contracts or grants. In 1999, the University of Colorado suspended its clinical research activities after the Federal Drug Administration (FDA) accused its Health Sciences Center of failing to maintain documents on research involving human subjects (Brainard, 1999). Suspension of research was also the case at Virginia Commonwealth University, The University of Pennsylvania, The Alabama University, and, most recently, Johns Hopkins University (Brainard, 2000a, 2000b, Brainard & Miller, 2000; Curry, 2001).

In the U.S, there is one additional remedy beyond sanctioning by the scientific

community: the judicial system. Plagiarism, for example, is not only a matter of misconduct, but also a criminal felony subject to legal processes. On the other hand, in Germany, scientific fraud is not in and of itself a crime (Bollag, 1998b).

Beyond the Hard Sciences

Sanctions need not and have not been limited to bio-medical protocols. In recent years there has been a growing number of cases of scientific misconduct among health and human services industries (e.g., nursing, psychology, and psychiatry), the predominant theme of which concerns plagiarism and/or falsification or fabrication of data. Table 3 summarizes some of the major scientific misconduct cases in these disciplines over the last decade. Unlike many cases of misconduct substantiated in the bio-medical fields, these cases were absent allegations of human subjects violations. However, findings of misconduct highlight the diligent reviews to which research reports are subject and the serious penalties that are levied when the ideas of others are appropriated or results falsified. Sanctions include forced resignations, criminal prosecution, ineligibility to receive publicly supported grants or serve on review panels, and remedial courses in ethics. These sanctions have widespread and serious implications for how research is conducted and highlight the potential consequences that may ensue when procedural and ethical breaches are uncovered.

INSERT TABLE 3 ABOUT HERE

Analysis and Application

The most significant lesson from these cases is the importance of ensuring that research review and monitoring procedures are devised, widely understood, and uniformly followed. To date, public disclosure of cases of scientific misconduct within the social and behavioral sciences have been relatively modest compared to such disclosures within the hard sciences. As Table 3 suggests, there are a number of U.S. cases of scientific misconduct in human service professions which touch closely on the work of the third sector. The vulnerability of some voluntary agencies to “wrongdoing” has already been substantiated, but such instances primarily concern managerial or financial improprieties (Gibelman & Gelman, 2001). A point of relevance, however, is the failure in such instances of the board of directors to adequately perform its monitoring and oversight functions. To the extent that voluntary agencies are engaged in research (even for purposes of program evaluation), boards may need to assess their role in monitoring this aspect of organizational functioning or establish a mechanism that can fulfill this function on the board’s behalf.

The research conducted by or on behalf of voluntary health and human service organizations involves interaction with populations that are often classified as vulnerable and confidentiality of data is often an issue. Direct observations, the administration of questionnaires, review of existing case records, or the introduction of therapeutic interventions and the use of control groups that do not receive interventions may be innocuous or, alternatively, may pose risks to the emotional, social, or economic well being of participants (Gibelman & Gelman, 2001). Deception, invasion of privacy, lack of informed consent, mandatory reporting requirements (such as cases in which potential child abuse is identified), or the loss of economic benefits (as may apply, for example, to the disabled or welfare recipients)

are all examples of harm that may result from faulty research designs or misconduct in the implementation of research protocols. Although substantiated cases to date fall outside of these human protection areas, the nature of the research conducted within the helping professions suggests the potential for such misconduct.

In the U.S., the federal government is tightening its oversight of research which involves research subjects considered to be among vulnerable populations, such as children, people with mental illness or developmental disabilities. The National Bioethics Advisory Commission, for example, has called for tougher regulations to protect the rights of people with mental illness who are recruited for research studies. Recommendations include participation of advocates for patients with mental illness or mental retardation on institutional review boards, as well as persons familiar with psychiatric research (Campbell, 1998). At issue is the perceived need for special protections for patients whose conditions or illnesses may prevent them from giving informed consent.

REVIEW MECHANISMS

The integrity of scientific research within the hard sciences is generally monitored by two primary and distinct sources: professional associations, through their applicable ethical codes, and institutional review boards (IRBs). These sources are applicable to third sector researchers who are affiliated with a hospital or university and work in concert with voluntary health and human service organizations. Even when a nation has developed or is working to develop research review procedures, it is unlikely that the jurisdiction of IRBs would extend to third sector research carried out under NGO auspices, unless a formal relationship is established with a hospital or university research center in regard to the specific research project.

Several countries have sought to develop institutional mechanisms to tackle scientific fraud. In the U.S., efforts in this respect have been ongoing since 1966 and continue in their refinement through today. In the United Kingdom, solutions to combat scientific fraud are being sought, with the impetus coming from the Committee on Publication Ethics (COPE), established by editors of leading medical journals (Hargreaves, 2001). Denmark, Norway, Sweden, and Finland have established committees to deal with scientific misconduct – to initiate preventive measures and/or to investigate alleged cases, but again with an emphasis on medicine and the hard sciences (Nylenna, Anderson, Dahlquist, Sarvas, et. al., 1999). Australia established the Australian Universities Quality Agency (AUQA) as an independent body to oversee and improve the quality of higher education, including jurisdiction over research. However, the AUQA was criticized as a paper tiger and as failing its first test -- the case of Bruce Hall, discussed below (Bradley, 2002). Germany has been working to develop review protocols for five years. German universities and research institutions are faced with a June 30, 2002 deadline to either adopt a scientific code of conduct or face a loss of government research funds (Perera, 2002). In Canada, too, a group of editors from health science journals formed, in 2002, an association to promote ethical behavior in research, peer review, and editing (Sibbald, 2002).

Although these efforts to institutionalize mechanisms by which to fetter out scientific misconduct are laudable, they are also the exception. In most countries, there is no coherent system to provide research oversight. Even if there was, it is unlikely it would apply to the third sector. The institutional mechanisms established by universities are only relevant to third sector research when the researcher is a part of that institution or when the research entails

collaboration between a university and one or more voluntary agencies. Complicating the situation is the duration of many of the investigations. One example comes from Australia. Bruce Hall, Chief Medical Director, New South Wales Faculty of Medicine was first accused of abusive (bullying behavior), misappropriating research funds, misconduct in scientific reporting, and scientific fraud in 1997 (Swan, 1997). Based on the findings of an internal investigation, five of the allegations were dismissed. However, it was determined that he had made mistakes for which he must apologize and make retractions. But the matter did not stop there, as a new independent inquiry was initiated (Zinn, 2002; Contractor, 2002; Stock, 2002) by the National Health and Medical Research Council. The New South Wales Health Department suspended him pending completion of inquiry (Benson, 2002). The matter is still open in 2002. The implication is not only for the person(s) accused, but also for the investigative bodies for which there are personnel, time, and dollar costs involved.

Institutional review boards have other limitations. In the U.S., the Office of Research Integrity and the separate IRBs of institutions are primarily concerned with government-funded research, although there is increasing impetus to involve IRBs in reviewing research protocols even when no federal funds are involved. (This consideration to expand jurisdiction to cover non-federally supported research is the result of the growing number of studies sponsored by private sources, including pharmaceutical companies, in areas such as genetic testing ["IRS and human cell research protocols", 2000]). Further, IRB reviews occur at the application stage, prior to the initiation of the research, with some attention to annual reviews that may be more or less perfunctory. However, most misconduct, as the sample cases demonstrate, is in the fabrication of data or falsification of findings, areas that are not within the purview of any current oversight source.

As the funding bodies that support third sector programs institute more and more accountability requirements, voluntary health and human service organizations need to increase their internal research capacity to keep pace. This capacity building progress may be internal only, or in collaboration with university-based or independent researchers. In this process, the organizations become subject to the same level of scrutiny as researchers in the bio-medical sciences.

An unknown proportion of third sector research may be totally absent of any oversight by any source. The need for such oversight may not be yet recognized in some instances. Internal or organizational-specific systems to prevent and, when necessary, address scientific misconduct may also be thwarted by a lack of organizational expertise and the practicalities of volunteer leadership, staff time and resources. In general, voluntary agencies will be ill-equipped to provide such resources. Without the procedures in place and a cadre of trained researchers available and able to review third sector research protocols, voluntary health and human service organizations may well be vulnerable to some of the questionable research practices that have been unearthed in other fields. There are also those who argue that when organizations serve as the "scientific validity police" of their own colleagues, they will either join ranks in defense, or, at the other extreme, find against their colleagues for fear of accusations of institutional bias (Block, 1991; Silbergeld, 1995).

DIRECTIONS FOR THE THIRD SECTOR

Given the relatively undeveloped, but now rapidly expanding third sector research

enterprise, there is a clear need for information about how research is monitored and reviewed, if at all. The number of publicized cases of wrongdoing in the hard sciences and, increasingly, in the professions, suggests that the third sector must understand the implications for its own research and take preventive steps. Mechanisms are needed to ensure that: (1) researchers are cognizant of the ethical issues involved; (2) the protocols meet established standards; and (3) findings are based on systematic and valid research.

Several of the professions included within the voluntary health and human services labor force (e.g., social workers, psychologists) are bound by their respective professional ethic codes. In the U.S., such codes encompass the area of ethical conduct in research. But the third sector is diverse, spanning an infinite number of areas ranging from the arts to preservation. In addition, volunteers and indigenous personnel may constitute a substantial portion of the labor force, depending on nation, organizational area of concern, and finances. The applicability, then, of any one professional code is essentially nil.

A code of ethics for the entirety of the third sector is unlikely, given the multiplicity of professional and non-professional personnel represented within it. A central question is: whose responsibility is it to monitor such protocols and review the research conducted and can mechanisms or processes be established that significantly reduce the risk of scientific misconduct in the third sector? An option lies with the development of international guidelines or standards. International organizations representing the third sector are the logical bodies to develop such standards, drawing on the work that has been done in various nations. Since the International Society for Third Sector Research is specifically focused on research within and of this third sector, it may well be the logical body to initiate such activity.

Prior to any effort to develop research standards for third sector research, the information base needs to be expanded to inform us about the current status of review procedures. Possible areas of inquiry include:

- C A cross-national and comparative analysis of the educational programs that prepare the third sector labor force, including programs of nonprofit management, social work, public health, and other represented disciplines, to ascertain the degree to which ethical conduct is a component of the curriculum.
- C A cross-national assessment, using a representative sample, of the familiarity of the third sector labor force (both paid and volunteer) with the components of appropriate scientific conduct.
- C An analysis, perhaps through the use of focus groups, of issues and obstacles to the conduct of ethical research within third sector organizations which result from the demands of external accountability bodies.
- C An investigation of the procedures used by nonprofits to review and monitor research conducted by or about the organization, including the scope of such reviews and the extent to which the validity of the science itself is considered.

The data emanating from such studies would provide the base for an informed assessment of the extent to which mechanisms for research review and monitoring are in place and how well they operate. The outcome of investigations addressing these and related issues will also help to define the parameters of scientific misconduct as it relates to third sector research and to elaborate on its meaning with some degree of precision.

Since allegations and, in some cases, findings of scientific misconduct are, by definition, after-the-fact of the activity, prevention is the logical area of focus. Educational programs that prepare the managers and practitioners of the voluntary sector need to assume initial responsibility for teaching research ethics, screening proposals to determine their validity from a “good research” perspective, and ensuring that collaborative research projects with third sector organizations are subject to the same level of scrutiny as are academic studies.

There are prototypes for the development of voluntary standards. In the U.S., for example, the Council on Accreditation for Services to Families and Children has devised a comprehensive set of standards covering all aspects of organizational functioning, including research; these standards are periodically revised to reflect new developments. This process of standards development can be emulated, but on an international level.

The third sector is world-wide and the “one size fits all” pattern of research review and monitoring is likely to fall short in regard to applicability and feasibility. Voluntary standards would acknowledge such distinctions in capability, but draw the line at basic expectations in regard to good empirical practice.

Once standards were established, an international research integrity office might function, through ISTR or a special volunteer association comprised of volunteer representatives internationally. Issues related to validity, methodology, consent, risks and benefits should all be screened prior to institutional review. The research-integrity office would serve largely a preventive function, but would also be called upon in cases of alleged scientific fraud.

At the agency level, mentoring provides a mechanism for research oversight. Administrators may sometimes be in a position to review and assess the integrity of research developed by staff. Institutionalizing mentoring relationships can mitigate some of the potential for fabricating or falsifying data, assuming, of course, the required level of expertise within the agency or access to consultation from outside the organization.

Mentoring may also lead to collaborative research and collaboration is one of the hallmarks of large scale research protocols. Personal and professional relationships built on knowledge of and respect for collegial expertise and integrity are an essential base for such collaborations and can develop from initial working partnerships. Such collaborations provide a system of checks and balances and set a tone for the way in which research is conducted. Maintaining original records involving questionnaires and consent forms may also mitigate against potential problems if questions about the research are raised.

CONCLUSION

Ethical research conduct has, by and large, been ignored, in part because of the early stage of development of the third sector research enterprise. However, the issue of research integrity takes on increasing importance as third sector research gains a legitimate standing in the conduct of scientific inquiry. This expansion of third sector research is not without risks.

Although the majority of publicized cases of scientific misconduct have centered largely on bio-medical research and the applied sciences, the circumstances associated with these

cases have strong implications for the standards to which third sector researchers will be held. Voluntary health and human service organizations are likely to experience a stronger imperative to engage in research as demands for accountability and documentation of the outcomes of services continue to grow. National and even international cases of scientific misconduct reveal the serious consequences to individual researchers and their employing institutions.

The substantial media attention to cases of wrongdoing have prompted some claims that concerns are overblown and that a few bad apples do not prove a rule. Perhaps with an eye to limiting the expectations of any potential oversight body, some commentators have sought to single out the medical establishment as the center of concern for monitoring (White, 2002). One can as easily hypothesize that the number of proven cases of misconduct are “the tip of the iceberg” rather than an over-reaction and unwarranted concern. When human life itself, let alone quality of life, is at issue, vigilance in monitoring is the preferred option.

The prevention of wrong doing takes knowledge, diligence, and oversight among researchers of all fields and professions. Regular forums for discussion about human experimentation as well as the applicable rules which govern it should be scheduled at all third sector research forums. Clear standards, widely publicized, and ongoing education regarding appropriate scientific conduct would help alleviate actual or potential problems.

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Table1
A SAMPLER OF SUBSTANTIATED CASES OF SCIENTIFIC MISCONDUCT: 1995-2002
UNITED STATES
BIO-MEDICINE AND “HARD” SCIENCES

Person/Institution	Field	Type of Misconduct	Outcome
Duke University Medical Center	Bio-Medical Research	Ethical and safety rule violations; faulty or absent informed consent documents	Temporary de-certification of all federally funded research
Gloria Clayton Medical College of Georgia	Nursing	Fabricated research process and data	Prohibited from receiving a federal grant or contract for 3 years
Caroline E. Garey, Doctoral Student, Boston College	Biology	Misrepresentation; fabricating data	Denied PhD; Agreed to exclude herself from federal grants or advisory posts for 5 years
Steven Arnold Tulane University	Toxicology	Insufficient data to support findings	Ineligible for federal grants or contracts for 5 years

Farooq Siddiqui Roswell Park Cancer Institute	Cancer Research	Misrepresenting data	Ineligible for federal grants or contracts for 2 years; to be supervised in his work for 2 years
Andrew Friedman Harvard Medical School	Reproductive Biology	Altered & fabricated data	Voluntary agreement to exclude from any contract with gov't for 3 years; thereafter to be supervised
David Siegel University of California, San Francisco	Cardiology	Plagiarism of grant application	Fired; letter of censure
Evan B. Dreyer Massachusetts Eye & Ear Infirmary, Harvard University-Affiliated	Not specified	Fabricated data	Ineligible for federal research funds for 10 years
Camran Nezhat Farr Nezhat Stanford University	Gynecology	Seriously deficient scholarship	Teaching privileges suspended

Joao Carlos deSales	Public Health	Falsified data	Fired
William A. Simmons, Post-doctoral fellow University of Texas, South-western Medical Center	Immunology	Manipulating results of experiments	Ineligible for federal grants or contracts for 5 years
Amitov Hajra	doctoral candidate	Fabrication of data	Barred from federally funded research for four years and denied his Ph.D.

Burd, 1995; Campbell, 1999; Carlsen & Russell, 2001; Dalton, 1997; Heredia, 2002; Hilts, 1999a, 1999b; Yachnin, 2000a, 2000b.

Table 2
A SAMPLER OF SUBSTANTIATED CASES OF SCIENTIFIC MISCONDUCT: 1995-2002
INTERNATIONAL
BIO-MEDICINE AND “HARD” SCIENCES

Country	Person/Institution	Field	Type of Misconduct	Outcome
Germany	Friedheim Hermann Ulm University	Molecular Biology	Fabrication of findings	Suspended; Suing for damage to his career
Germany	Marion Brach Ulm University	Molecular Biology	Fabrication of findings	Fired
Germany	Roland Mertelsmann Ulm University	Molecular Biology	Failure to obtain informed consent; manipulation of data	Suspended from research duties
UK	Peter Seeburg Max-Planck Institute for Medical Research	Public Health	Falsifying data	Confessed 20 years later; formal censure
Sweden	Ulf Lonn Karolinska Institute	Oncology	Falsification of data; destruction of original data	Unclear
UK	Peter Rolfe Keele University Research Center for Science and Technology in Medicine	Biomedical Engineering	Misappropriating research funds	Ten months in jail; repayment of \$90,000
South Africa	Werner Bezwoda WITS University	Oncology	Manipulation of clinical trials; falsification of findings	Fired

Japan	Shinichi Fujimura	Archeology	Planted findings; Fraud	Apologized; dropped from view; reportedly in mental hospital
China	Pan Aihua	Molecular Biology	Plagiarism	Fired
UK	Geoffrey Fairhurst General Practitioner	Physician	Violated informed consent; falsified results	Licensed revoked
Poland	Andrzej Jendryczko Medical University of Silesia	Biochemistry	Plagiarism	Right as an independent researcher revoked
Canada	Ronan O'Hagen, PhD Student, McMaster Univer.	Cancer research	Data falsification	PhD on hold
China	Wang Mingming Peking University	Anthropology	Plagiarism	Not fired, but removed from chairing university's Folklore Institute
Australia	Bruce Hall Department of Medicine, Liverpool Hospital, University of New South Wales	Immunology	Errors in attribution of authorship; poor working relationships	Suspended; formal apology required; remedial training; monitoring
UK	Malcolm Pearce, Isaac Manyonda, & Geoffrey Chamberlain St. George's Hospital	Gynecology	Fraud; falsification of study process and findings	Pearce - fired Chamberlain - resigned Manyonda - no action

Abbott, 1998; Atterstam, 1997; Benson, 2002a, 2000b; Birchard, 2001; Buist, 2000; Contractor, 2002; "Feds punish scientist for bad research," 2002; Hagman, 2000; Hazelton, 2001; Heredia, 2002; Koenig, 2001; Lin-Liu, 2002; Maugh & Mestel, 2001; "Researcher rebuffed", 1999; Richmond, 1995; Sidley, 2001; Steimle, 1998; Stock, 2002; UNSW (2002); Weber, 2001; "WITS fires cancer researcher", 2000; Zawadzki, 1998; Zinn, 2002.

Table 3
Selected U.S. Examples of Scientific Misconduct in
Fields Related to Health and Human Services

Year	Institution	Investigator	Discipline	Allegation	Sanction
1998	University of Pittsburgh	Stephen Breuning ¹	<u>Psychology</u>	<u>Falsification & fabrication of data</u>	<u>Criminal charges; fine</u>
<u>1991</u>	<u>Not publicized</u>	<u>Arnold Rincover^b</u>	<u>Psychology</u>	<u>Plagiarism; falsification of data</u>	<u>Resignation</u>
<u>1991</u>	<u>Not publicized</u>	<u>Lonnie Mitchell^b</u> <u>Jerusa Wilson^b</u>	<u>Psychology</u>	<u>Plagiarism; inadequate supervision</u>	<u>Reprimand; barred from serving on Public Health Service (PHS) advisory panels</u>

<u>1991</u>	<u>Stanford University</u>	<u>Phillip A. Berger^b; Stephen M. Stahl^b</u>	<u>Psychiatry</u>	<u>Plagiarism; misrepresentation of status of research subjects</u>	<u>Resignation; barred from receiving federal grants or serving on PHS Advisory panels; monitoring</u>
<u>1995</u>	<u>Medical College of Georgia</u>	<u>Gloria Clayton^c</u>	<u>Nursing</u>	<u>Fabrication of subjects and data</u>	<u>Barred from receiving grants and serving on PHS panels</u>
<u>1996</u>	<u>University of Arizona</u>	<u>Victoria Santa Cruz^d</u>	<u>Nursing</u>	<u>Fabrication of data</u>	<u>Barred from receiving grants and serving on PHS panels</u>
<u>1996</u>	<u>Indiana University - Perdue</u>	<u>Harry L. June^d</u>	<u>Psychology</u>	<u>Falsified letters</u>	<u>Barred from receiving grants or serving on panels; course in research ethics; supervision</u>
<u>1999</u>	<u>University of Illinois at Chicago</u>	<u>Rocio del Carmen Restrepo^e</u>	<u>Psychology</u>	<u>Fabrication of data</u>	<u>Barred from receiving grants or serving on PHS panels; supervision</u>

^aBurd, 1994; ^bWheeler, 1991;. ^cBurd, 1995; ^dWalker, 1996; ^eCampbell, 1999.