Society for Scientific Values

Ethics in Scientific Research Development and Management

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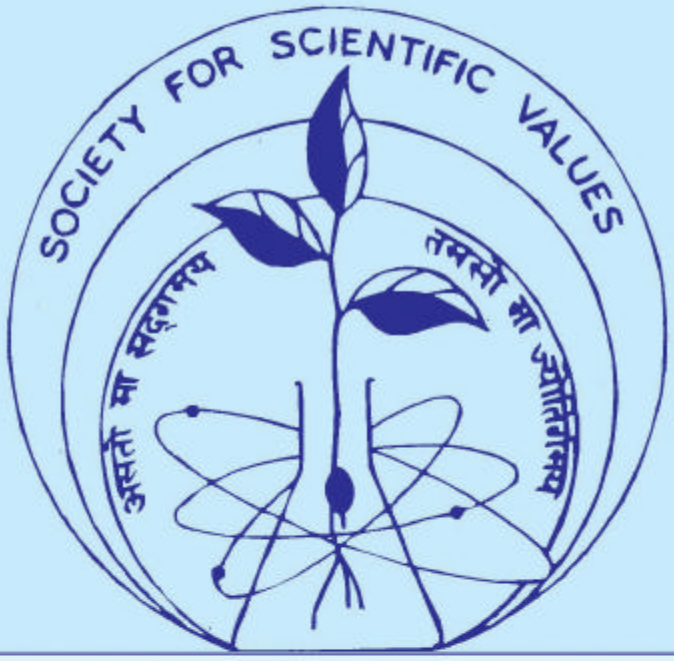

Lead us from unreal to real

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Main objectives of the 'Society for Scientific Values

1. To promote objectivity, integrity and ethical values in pursuit of scientific research, education and management, and
2. To discourage the unethical acts in these areas.

Research Integrity and Scientific Values: A comparison of American and Indian models

Dr. N. Raghuram*

The 2004 ORI Research conference on Research Integrity (November 12-14, 2004, San Diego, California, USA) provided a unique opportunity to understand the American government model of promoting scientific values and compare it with the Indian system. This was the first time that the organisers decided to invite a few international participants to an otherwise primarily US activity. Being the only Indian delegate at the conference, I was able to present some Indian case studies and the pioneering role of the Society for Scientific Values to deter misconduct and promote integrity in Indian science. The following report is intended to share some crucial insights into the working of the American system and its relevance to India, if any.

The main organiser of the conference was the Office of Research Integrity (ORI) under the US Department of Health and Human Services (HHS), which oversees adherence to scientific values in the U.S. biomedical research. It spends about $ 2 million per annum (2004 data) to support research about ways to foster integrity and deter misconduct in research. One of the major activities of ORI is to develop a knowledgebase for making responsible decisions about the best ways to promote and ensure high integrity in the nearly $30 billion annual federal funding (2004 data) for biomedical and behaviour research supported by HHS (See box for a history of the ORI and its limited scope). The ORI Research Conferences on Research Integrity bring together ORI-funded researchers and other scholars interested in integrity in research to discuss crucial research problems, explore different research methods, and share research results. The latest conference was held at the Paradise Point Resort and Spa, San Diego, California during November 12-14, 2004. It was Co-Sponsored by the University of California - San Diego, Association of American Medical Colleges, American Association for the Advancement of Science and Merck Research Laboratories.

One of the most striking revelations about the US system is that unlike the Society for Scientific Values, which was started by Indian Scientists who believed that self-regulation is the best regulation, ORI was instituted by the US government, concerned over fraud in US science. This could either be a credit to the concern of Indian scientists, or the Indian government's lack of it. There is no evidence of any US society comparable to the Indian SSV, nor such a prominent involvement of other US professional academies and societies with issues of scientific values.

Advantages of the ORI model: The advantage of a strong government involvement in the US is obvious: it attracted a lot of social scientists, psychologists and concerned

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biomedical scientists to get into the whole issue of research integrity with rigorous scientific analysis in project mode, with funding upto $1,75,000 per year per project. Other advantages of government involvement include uniform procedures, guidelines, incentives/disincentives, administrative teeth and some sort of public accountability through the US congress. A cursory glance at the titles of papers presented at the conference reveals the range and scope of the issues being investigated, the methodologies being used, and even attempts to put together common standards, terminology and definitions.

Some of the research questions that are being investigated include: How much misconduct is happening and what is the level of variations among institutions? What types of misconduct are being reported? Are they increasing or decreasing with time, training, funding or career security? What is the cost of sloppy or fraudulent research to the American exchequer? When and how do researchers learn about good research practices? What are the factors that encourage or discourage researchers from following these practices? How serious is the role of source of funding or conflict of interest in determining the outcome of research? Which levels of the research hierarchy indulge most in misconduct? Which sections of the research community blow the whistle most often, and which sections make the most successful allegations (as proven by subsequent enquiries)? How critical is the need to protect the whistle blowers? To what extent do ethnic or past cultural backgrounds influence the researcher's conduct? What is the role of education/training in promoting responsible conduct of research? How critical is the role of the mentor? What policies do research journals need to prevent/ reject publication of manipulated data or just questionable research results?

While these questions may be just as relevant for us here in India, over a decade of research in the US has not yielded definitive answers to most of these questions. However, some trends are revealing: The most funded and the best-ranked institutions also have some of the most frequent reports of misconduct cases. Higher educational institutions such as universities rank highest in terms of misconduct, as compared to other research institutions. Falsification, fabrication and plagiarism (FFP) constitute the most reported types of misconduct. At least half of the misconduct cases are due to bad record keeping. The rate of misconduct decreases with increasing career mobility. Larger panels or durations of enquiry don't necessarily lead to more convictions. The most frequent whistle blowers are from the faculty, but the most successful whistle blowers are students/post-docs. Whistle blowers are not often encouraged by reward or discouraged by victimisation. Mentoring does much more to research integrity than rules, regulations and education/training, but absentee mentoring is a major problem; many good mentors were not mentored themselves.

Most of the above generalisations have been arrived at using survey methodologies, with their attendant limitations. Very few studies provided deeper insight through detailed case studies. Interestingly, while scientists make most of the noises about authorships and plagiarism, the final outcome of research (and therefore the common man) is most adversely affected by falsification and fabrication. Similarly, there are other questionable research practices (QRP) that are probably more frequent than FFP but not very well defined or understood. Similarly there are wider issues of responsible conduct of research (RCR), which are not addressed adequately. There are also issues of terminology and standard

vocabulary that need attention. Most importantly, there is not clarity yet on the causes for misconduct, or the most effective means for prevention. The SSV could benefit greatly from these experiences.

Disadvantages of the ORI model: ORI is concerned with integrity only in biomedical research, that too only those programs/institutions funded by federal PHS grants. This means that adherence to scientific values in other areas of science, or even in biomedical research supported by private agencies or other non-PHS sources, are not necessarily the responsibility of ORI. Every institution that seeks/receives PHS grants is required to have its own institutional ORI, to provide training in research integrity, as well as to investigate complaints and report to the federal ORI. Again, these institutional ORIs, may or may not cover other areas of science, or even biomedical research supported by private agencies or other non-PHS sources. It is expected that depending on the level of concerns on research integrity that emerge in other areas of science or for that matter even social science, ORI-like bodies or other suitable mechanisms will be instituted by the concerned federal and/or state agencies. This will lead to unnecessary bureaucracy with either tremendous redundancies or multiplicities in regulatory mechanisms to deal with what seems to be an essentially common problem of research integrity and scientific values.

One of the main pillars of the ORI model for fostering integrity is to make the employers have institutional ORIs, policies and training programs in place. This works on the assumption that the government, employers or heads of institutions are keen to promote integrity, anxious to enquire into allegations of misconduct and prompt to take action to deter misconduct. For us in India, the experience of SSV as well as that of this author shows that none of the above assumptions are true. Therefore, institutional ORI model does not work in India, even if we avoid redundancies and have a single ORI in each institution to deal with all areas of science and technology under its ambit. What we need is a mechanism to provide more teeth to SSV or other such scientific Academies/societies that are completely independent from government or individual research institutions.

How do Indians fare in the US in terms of their record of research integrity? It is difficult to get a very satisfactory answer to this straight but sensitive question. Some say Indians in the US are just as bad or perhaps worse in terms of their research integrity record. Others say that there is no clear basis for such generalisation, as collecting ethnic data on issues of research integrity is considered politically incorrect. But it is generally acknowledged that in an increasingly globalising world depending on overseas scholarships and collaborations, mentoring and research practices in one country tend to influence the research outcomes in other countries, and therefore every country needs to be cautious about the reputation of its students and scientists on issues of integrity. To that extent, ORI seems to be open to having joint conferences/exchanges with similar bodies in other countries. What is most heartening to note is that there are many Indian names conducting studies and co-authoring publications on research integrity in the US, some of them even working with ORI funds! Perhaps SSV should approach them for membership and improve our international outreach.

Box: The History of ORI (USA)

The Office of Research Integrity under the US Department of Health and Human Services (HHS), which oversees adherence to scientific values in the U.S. biomedical research, has its origins in the US Congressional hearings on fraud in science. The process began in 1981 when then Representative Albert Gore, Jr., chairman of the Investigations and Oversight Subcommittee of the House Science and Technology Committee, held the first hearing on the emerging problem. The hearing was prompted by the public disclosure of scientific misconduct cases at four major research centers in 1980. There were at least 12 cases of scientific misconduct disclosed between 1974-1981, and additional allegations involving researchers from National Institutes of Health (NIH), universities, and other research institutions in the US throughout the 1980s continued to attract Congressional attention.

In order to address the emerging problems, a series of regulatory measures were initiated by the US government, especially the Rule concerning "Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science", for NIH and others funded by the US Public Health Service (PHS), such as The Centers for Disease Control and Prevention, The Food and Drug Administration (FDA), The Substance Abuse and Mental Health Services Administration, The Health Resources and Services Administration, The Agency for Healthcare Research and Quality, The Agency for Toxic Substances and Disease Registry and The (Red) Indian Health Service. The regulatory activities of the FDA have been exempted from the responsibilities of research integrity.

Before 1986, reports of scientific misconduct were received by funding institutes within Public Health Service (PHS) agencies. In 1986, the NIH assigned responsibility for receiving and responding to reports of scientific misconduct to its Institutional Liaison Office. This was the first step taken to create a central locus of responsibility for scientific misconduct within the US Department of Health and Human Services. In March 1989, the PHS created the Office of Scientific Integrity (OSI) in the Office of the Director, NIH, and the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for Health (OASH). The sole purpose of these offices was to deal with scientific misconduct and relieve the funding agencies from carrying out this responsibility. In May 1992, OSI and OSIR were consolidated into the Office of Research Integrity (ORI) in the OASH. Later that year, HHS established a hearing opportunity for all scientists formally charged with research misconduct. Next year, President Clinton signed the NIH Revitalization Act of 1993, which established the ORI as an independent entity within the Department of Health and Human Services (HHS). The Act also mandated that a Commission on Research Integrity be created to review the system for protecting against scientific misconduct. The Commission delivered its report to the Secretary of Health and Human Services in November 1995. The Commission made 33 recommendations including the development of a regulation on the protection of whistleblowers in research misconduct cases and the extension of the misconduct in science assurance that required institutions to establish educational programs on the responsible conduct of research (RCR). Based on the subsequent review of these

recommendations, HHS announced several changes in 1999 to promote research integrity, which include:

1. The HHS adopted the proposed governmentwide definition of research misconduct developed by the National Science and Technology Council that was published in the *Federal Register* on October 13, 1999. The final definition was published in the *Federal Register* on December 6, 2000.

2. The primary responsibility of extramural institutions and intramural research programs for responding to allegations of scientific misconduct was reaffirmed. The Office of Inspector General, HHS, rather than ORI was given the authority to conduct any fact-finding for the federal government. ORI continued to conduct oversight reviews of all investigations.

3. The Assistant Secretary for Health, upon recommendations from ORI, was delegated the authority to make final decisions regarding scientific misconduct and administrative actions, subject to appeal.

4. The role, mission and structure of the ORI was focused on preventing misconduct and promoting research integrity principally through oversight, education, and review of institutional findings and recommendations.

5. The HHS Departmental Appeals Board continued to hear appeals, but the hearing panels were to include two scientists rather than one or none.

6. All extramural research institutions were required to provide training in the responsible conduct of research to all research staff who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training, support by PHS funds or who otherwise work on PHS-supported research projects even if the individual did not receive PHS support. The *PHS Policy on Instruction in the Responsible Conduct of Research* was published in the *Federal Register* on December 1, 2000, and suspended on February 20, 2001, pending review of the substance of the policy and whether the document should have been issued as a regulation rather than a policy. The policy remains suspended.

7. The HHS published a notice of proposed rulemaking on the protection of whistleblowers in research misconduct cases in the *Federal Register* on November 28, 2000; the comment period ended on January 29, 2001. A final rule on the protection of whistleblowers is pending.

ORI carries out its responsibility by: developing policies, procedures and regulations related to the detection, investigation, and prevention of research misconduct and the responsible conduct of research; reviewing and monitoring research misconduct investigations conducted by applicant and awardee institutions, intramural research programs, and the Office of Inspector General in the Department of Health and Human Services (HHS); recommending research misconduct findings and administrative actions to the Assistant Secretary for Health for decision, subject to appeal; implementing activities

and programs to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and improve the handling of allegations of research misconduct; providing technical assistance to institutions that respond to allegations of research misconduct; conducting policy analyses, evaluations and research to build the knowledge base in research misconduct, research integrity, and prevention and to improve HHS research integrity policies and procedures; assisting the Office of the General Counsel (OGC) to present cases before the HHS Departmental Appeals Board; administering programs for: maintaining institutional assurances, responding to allegations of retaliation against whistleblowers, approving intramural and extramural policies and procedures, and responding to Freedom of Information Act and Privacy Act requests.

SSV Seminar on Bioethics: A Report

The Annual General Meeting of the Society for Scientific Values was preceded by a Seminar on Bioethics on 29th April 2005, held in collaboration with the Indian Agricultural Research Institute (IARI), New Delhi, which is celebrating its centennial year. The half-day seminar in the seminar hall of the Nuclear Research Laboratory of IARI was attended by scores of SSV members as well as students and faculty from Delhi and elsewhere. The President of SSV, Prof. K.L. Chopra, welcomed the distinguished speakers and the gathering, and underscored the importance of bioethics for India today and its relevance to the activities of SSV. In his introductory remarks, Prof. Nagarajan, Director of IARI, drew the attention of the gathering to the importance of ethics in the transfer/exchange of biological materials, especially between countries. He also lamented on the unethical violation of geographical indications in the case of products such as Darjeeling tea, Mysore silk etc. The inaugural address was delivered by Dr. V.L. Chopra, distinguished agricultural scientist and former DG, ICAR & Secretary to GOI and currently Member, Planning Commission. He eloquently diffrerentiated the concepts of morality and ethics on the basis of faith vs. reason, private vs. public, and local vs. universal. He argued that ethics is based on rational principles and therefore enjoys far more uniform and universal appeal than morality.

The next speaker, Dr. S. Natesh, Advisor, Department of Biotechnology, Govt. of India, gave an excellent overview of the growing prospects of biotechnology in India and elsewhere and the ethical concerns that they generate. He underscored the importance of public perception in the acceptance of any technology and the need for criticism and debate as its safety valve in any democracy. He presented ethics as a dillemma, citing gene therapy, stem cells, cloning, designer babies, organ transplatation and molecular pharming as examples. He also dwelt briefly on the linkages between ethics and equity, access, intellectual property rights, plant variety protection, biodiversity and indigenous knowledge. He cited the example of Arogyapacha as an ethical case of biosprospecting using indigenous knowledge of the Kani tribe in Kerala, who received a share of the commercial benefit through their tribal cooperative.

This was followed by a PowerPoint presentation on the topic “Bioethics, Biosafety and Scientific Values” by Dr. N. Raghuram, Reader, School of Biotechnology, Guru Gobind Singh Indraprastha University, Delhi. He listed the basic principles of bioethics and characterized the bioethics debates into three levels: philosophical, professional and regulatory levels. He argued that in India, the professional and regulatory ethics need more urgent attention as they affect public interest in a more direct and immediate sense. He listed some contentious issues of biosafety in the context of regulatory ethics and quoted examples of clinical trials of unapproved drugs, stem cell therapies, questionable environmental impact assessments etc. He also dwelt on issues of biopiracy and traditional knowledge, and the link between globalisation, biotechnology and private monopoly. He urged the Society for Scientific Values to take up issues of professional and regulatory ethics in biotechnology in public interest.

The seminar provoked some lively discussions and ended with vote of thanks by Dr. P.S. Datta, Secretary, SSV.

Newly constituted Executive Council of SSV
(August 1, 2005 - July 31, 2008)

President	:	**K.L. Chopra** (Former Director, IIT Kharagpur)
Vice-President	:	**Vikram Kumar** (Director, NPL)
Secretary	:	**Nandula Raghuram** (Faculty, GGS Indraprastha University, Delhi)
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		K Satyanaryana (DDG, ICMR, Delhi)
		B.B.C. Tilak (Library of Congress, American Centre, Delhi)
Special Invitees	:	**P.N. Srivastava** (Former Member, Planning Commision & Former VC, JNU)
		A.R. Verma (Former Director, NPL)