The Role of Transparency in Industry and Government E-governance Research and Applications

Stan Kachnowski[123] and Shubhendu Pathak[4]

ABSTRACT

Research into the field many areas life science and medical research has greatly benefited from the oversight of Institutional Review Boards (IRBs), also known as Ethical Review Boards, and the publication of results in peer reviewed journals. The review processes of research studies have never been more rigorous. There is need for a careful examination of these processes to reflect upon their application and impact on the general eGovernance landscape. This paper discusses how government and industry sponsored eGovernance research can borrow some of the processes from the IRB approval and peer review model currently used in academic and health care research. Greater participation by academia, even if government mandated, in the review and publication in eGovernance research could ensure greater transparency in e-Governance applications and accelerate the development and quality of the field.

Keywords: Institutional Review Board (IRB), Independent Ethics Committee (IEC), Peer Review, e-Governance, Health Care

1. Introduction

An Institutional Review Board (IRB) is a generic name used to refer to committees designated to approve, oversee and review research involving human subjects [1,2,3]. The committees are also known as Independent Ethics Committees (IECs) or Ethical Review Boards (ERBs). IRBs are designed to protect the rights and welfare of human subjects, assure proper evaluation, and oversee statistical models in analysis for biomedical, behavioral and other research studies [3]. Research conducted for a continuous analysis of eGovernance applications has been stressed in health care [4]. Also, ethical aspects become important as research in the field of eHealth Care opens new challenges to patient interests [5]. IRBs, which oversee research are thus expected to play a vital and evolving role in research in the field of eHealth.

The Peer review process pervades all academic disciplines and includes the examination by subject matter experts of the concerned field, of written documents submitted by authors on their proposed or executed work.. The objective of a peer review process is to cull out unwarranted claims and studies, allow dissemination and archiving of information that meets accepted standards and assign credit and priority to the work done by the author(s). [6,7,8] Rapid sharing and availability of information require that the information being made available to the scientific community and ultimately to the public is scrutinized, so

[1] Visiting Professor, Indian Institute of Technology, Hauz Khas, Delhi, India
[2] Fellow, Royal Society of Medicine, England
[3] Chair, Healthcare Innovation Technology Lab, New York, USA
[4] Manager, Research and Operations, Healthcare Innovation and Technology Lab, India

that only valid and relevant research is published.. Peer review not only ensures this paramount interest of the readers of the scientific community but also encourages authors by giving them proper and timely credit for their work.

EGovernance initiatives currently lack a standard framework for methodical evaluation and statistical modeling and a credible source for referring to prior research studies. [19] This research paper discusses how the review processes have been able to monitor and address critical issues in applications of health care eGovernance and proposes the use of similar review processes to endorse transparency in all eGovernance applications.

2. History of Institute Review Board (IRB)

The Nuremberg code was developed by the Nuremberg Military Tribunal as a standard to judge the experiments on humans conducted by the Nazis during the World War II. It serves as a landmark document in medical ethics [9]. According to the Hastings Center Report, the need for IRBs was first felt in the United States after revelations concerning the infamous Tuskegee experiments came to light. The Tuskegee experiment concerned questionable methods of treatment for syphilis among underprivileged African Americans. [10]. The Belmonte report titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" was created in 1979, following the publicity which accompanied this incident. The report is a cornerstone in medical ethics and outlines ethical principles of human subject protection. [11] The three basic principles identified in the report are:

- Respect
  - Humans should be treated as free thinking individuals capable of making informed decisions about their involvement in research studies
- Beneficence
  - The risk benefit ratio in the studies should be maintained at acceptable levels
- Justice
  - The selection of subjects should be equitable and warranted

The primary objective of IRBs is to protect the interests of humans involved as subjects in research studies. The role of IRBs can be classified into two categories, Initial Review and Continuing Review.

Initial Review involves review and approval of a research plan prior to the commencement of the research. This includes an examination of the research protocol, the informed consent documents, advertisements used to inform and recruit subjects, etc. This board makes sure that the risks involved in the research are justified in terms of anticipated benefits and that these risks are conveyed in the informed consent documents with adequate clarity. The board also ensures that advertisements are not misleading and that the selection of subjects is fair and warranted. The focus of the Initial Review is to thoroughly examine the informed consent documents. The reason for such focus is that the majority of subjects may not completely understand the risks involved in the research, and their expectations from the studies may be unrealistic. The statistical and evaluative review becomes even more important in the Indian context given the budgets allocated over the next year for development and implementation of eGovernance projects and the importance of these eGovernance initiatives in assisting various populations in need over the next year.

Continuing Reviews are conducted by IRBs during the research, as the board reviews any changes made in the research plan during the study and examines any unexpected experiences by research subjects reported during the course of the study.. The frequency of a Continuing Review depends upon the risks involved. The reviews are conducted more frequently if the risks involved are high. The board makes sure that the interests of the subjects are protected throughout the study by ensuring that the risk-benefit ratio of the research remains acceptable. Continuing Review serves as a safety net by identifying the risks that are not

adequately addressed during the initial review process and determining whether it is safe to continue with the research. IRBs are mostly associated with hospitals and academic centers. A few of the boards also exist with managed care organizations, government agencies and even for-profit organizations. [3]

IRBs and the Research in Health Care eGovernance

In healthcare eGovernance, the review process monitors and addresses two central issues of patient confidentiality and control group design, that come under come under informed consent and research protocol design of the IRB review. (Figure 1)

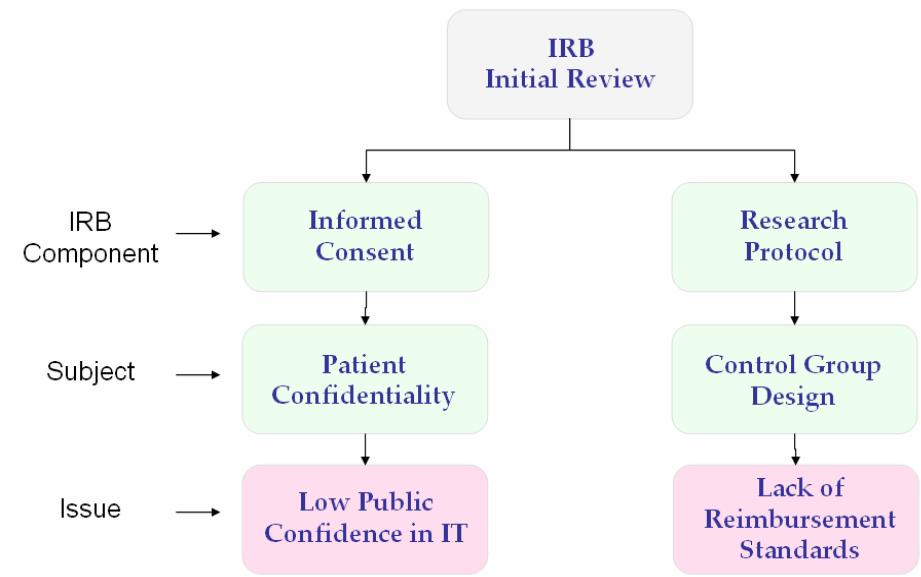

Figure 1: IRBs and the Research in Health Care eGovernance

Patient confidentiality in eGovernance research is critical, especially considering the transactions many citizens conduct during these various eGovernance applications, tests and research. The initial review makes sure that the informed consent documents are valid and reliable.[3] Patients may not completely comprehend the implications of their decision. This is especially true for interventions like telemedicine that are relatively new to the end users.. It is necessary that the content of any informed consent form is clear to the subjects [13].

Patient confidentiality has been a central issue in medical ethics since the time of Hippocrates. [14] Patient confidentiality faces new challenges in ehealth care. Health care professionals providing telemedicine services must ensure that confidentiality is maintained in their services. Whenever possible, information should be utilized in a manner which conceals the identity of the patient, as low public confidence in information technology is one of the issues surrounding telemedicine.

Control groups design in a research study should, in general, include the care that is given to subjects in absence of the intervention that is being studied. Control group for a health care eGovernance application can include:

- No care at all
- Inadequate local personal care
- Remote personal care requiring travel by patients

- Delayed remote personal care requiring travel by patients
- Delayed local personal care requiring travel by physician

The central issue surrounding the design of control groups for the applications that is addressed by IRBs is the lack of standards for third party reimbursement. Reimbursement differences are a primary confounding variable that can impact acceptance of the intervention by physicians and hospitals. Thus, the evaluation of an application will not be reliable when the "usual care" is reimbursable while telemedicine is not [15].

3. Peer Review, History and Role

Available texts concerning ninth century medicine as practiced in Syria, contain reviews of notes on treatments administered by physicians of that time. The notes were reviewed by local medical councils in order to judge whether a physician was competent to continue in the medical profession or to prosecute physicians for committing malpractice. It is believed that the first peer reviewed article was published in the year 1731 by the Royal Society of Edinburgh. The modern peer review process is an evolved form of this eighteenth century review. The most established texts on modern peer review process are Ziman (1968), Ravetz (1973) and Meadows (1974).

Peer review process is applied in different areas, including publication of articles in journals, papers submitted for conferences and proposals for approval of research grants. Journals are usually owned by professional societies and for-profit publishing companies. In either case, the staff at a journal's office is responsible for managing and processing the manuscripts sent to the office for publication. The majority of the staff at a journal's office are generally composed of people without scientific backgrounds, although there may well be those with such backgrounds among the editorial board.

There is a standard procedure of peer review of scholarly literature followed, with minor variations, by journals all over the world. Documents submitted at a journal's office are first examined by the editor of the journal. The editor carries out a preliminary examination to determine whether the report is worthy of further consideration. The preliminary examination includes determining whether the reported study lies within the scope of the journal's interest and ensuring that the report is of acceptable quality.

Reports that pass the first examination by the editor are sent to subject matter experts, usually two or more in number, for their comments. The experts, unlike editors who receive an honorarium, are not paid for reviewing the documents. The identity of the experts examining the report is usually not revealed to the author. There can be other arrangements as well which include double blind refereeing in which the identity of the author is also hidden from the referee and open refereeing in which the identity of the referee is revealed to the author. The experts examine the reports in detail and classify them as not publishable, publishable with changes or immediately publishable. Journals also have a final decision- making body which consists of one or more editors. That body makes the final decision on whether the article will be published. It is estimated that 80% of the papers receive recommendations for revisions.[8] The rigorous peer review process has the potential to encourage and uphold transparency both in research as well as the resulting applications of eGovernance.

There are several issues associated with the peer review process which have been the subject of active debate in the scientific community. These issues will also become a concern in the rapidly evolving field of eGovernance. A report published by Williamson et al in the year 2002 captures the major issues concerning the peer review process as: "*subjectivity, bias, abuse, detecting defects and fraud & misconduct."* Scientific studies also reveal that researchers do not easily accept new ideas, even when presented with new evidence, thus making it difficult for new ideas to gain public acceptance. Accordingly, peer reviews are also criticized for discouraging young scientists with new ideas.

4. Research in Health Care, Lessons for eGovernance

The change in the information sharing landscape in health care with the advent of the internet has made peer review an even more important concept for the scientific community. Rapid sharing and availability of information facilitated by the internet requires that the information being made available to the scientific community and ultimately to the public be scrutinized, so that only valid and relevant research is published. Peer review not only addresses this paramount interest of the readers of the scientific community but also inspires the authors by giving them proper and timely credit for their work. Further, it provides credible sources of reference of research studies in different application in health care eGovernance.

The growth of eGovernance in the developing countries has been unprecedented. With huge investments being made in eGovernance, the need of a review process for research and applications in the field is now being felt. eGovernment models that are successful in the developed countries will not necessarily repeat their success in the developing world and a review process is required to evaluate and assess the impact of these technologies on the new landscape.

EGovernment evaluation ` and there is a need to develop standard evaluation methodologies. [28[Current evaluations methodologies being used to evaluate eGovernance initiatives by the public sector in developing countries lack standard frameworks and the results of research being conducted are not credible.[19,20]. United Nations Development Programme (UNDP) has taken initiatives to develop assessment framework for eGovernance. [29]. Evaluation methodologies are also being developed at different levels in many countries across the globe. [30-34]

The western Asian countries have registered a 5% increase in eGovernance services in the past three years. India has been overtaken by 26 nations in eGovernment readiness in the same period and transparency has been cited as a growing concern in the subcontinent. [21,22] In the current scenario the eGovernance model in the developing as well as the developed countries can potentially benefit from the research model followed by the health care industry particularly for eGovernance in health care. A comparison between the research model currently followed by the industry and academia is shown in Figure 2.

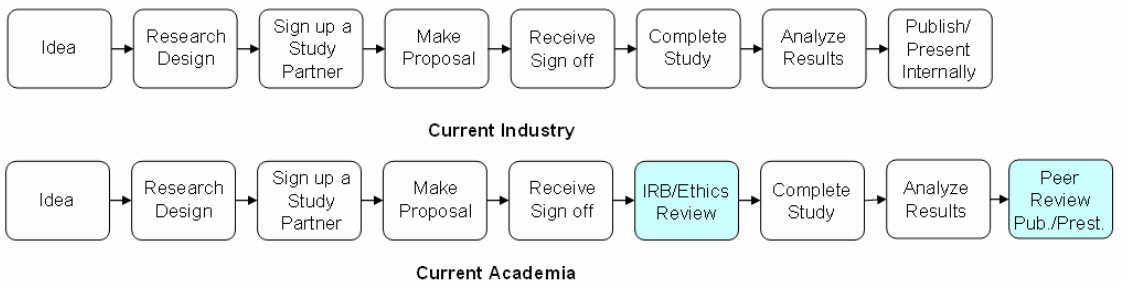

Figure 2: Research Model Followed by the Industry and Academia

The critical issues that the IRB and the peer review process addresses were previously discussed. We now discuss how these processes can be borrowed by all the eGovernance applications to uphold transparency in these applications. There are three vital components of the process that should be considered while borrowing the review process for all eGovernance applications. The three components are methodical evaluation, statistical modeling, and funds.

Methodical Evaluation and Statistical Modeling

Methodical evaluation and statistical modeling are important processes both of IRB and the Peer review. In an academic research methodical evaluation and statistical modeling of eGovernance applications are likely

to look into the following aspects, each in comparison to other "non e" alternative(s) available. [18]

i. Evaluation based on health outcomes of eHealth intervention
   - The impact of the eHealth intervention on the clinical process
   - The effect of the intervention on long term and immediate health outcomes

ii. Evaluation based on health care access
   - The effect of eHealth intervention on use of services
   - The effect of eHealth on efficiency of the services

iii. Evaluation based on cost effectiveness
   - The costs that the application incur on the health care provider
   - The costs that the application incur on the patients
   - The overall cost benefits to the society and the health care industry
   - The cost of the application in relation to its benefits

iv. Evaluation based on patient's perspective
   - Thematic analysis of patient satisfaction surveys
   - Evaluation based on clinician's perspective
   - Thematic analysis of patient satisfaction surveys

Inclusion of these components in a review has the potential to encourage transparency in eGovernance tools and applications.

Funds

The added cost and resources entailed in bringing an IRB type review process at the beginning of a study and a peer review publication process at the end, would be minimal. They would not be burden on the industry considering the assurance that these review processes bring to address the urgent need for transparency in eGovernance application in developing countries.[21,22] The planning commission and the Department of Information and Technology, Government of India has also stressed the need for transparency in eGovernance.[23]. IRBs have been widely criticized for being expensive and failing to address certain vital issues. [24,25,26] The idea is not to emulate IRBs but to learn from them so as to be able to effectively address the problems associated with transparency of eGovernance research and applications. Borrowing specific components like that of methodical evaluation and statistical modeling is likely to be cheap and cost effective. The cost effectiveness of the peer review system has also been emphasized in the scientific community.[27] Besides, peer reviewed publications facilitate credible sources of learning from the mistakes of others, thereby adding to the overall cost benefits to the industry and government. Given its tendency toward ethical validation, study design and peer review, the academic community, and specifically more experienced professors, have the ability to provide these skills to government and industry.

5. Concluding Remarks

eGovernance has witnessed a rapid growth throughout the world in the past decade and little doubt remains as to its prevalence and growth in the future. The amount of investments being made in eGovernance is unprecedented especially in the developing countries. A critical issue faced by the industry is that the success models of the west cannot be simply copied for use in the developing countries as there are unique issues which surround the research and applications of eGovernance in these regions. The need for additional transparency in the research and development of e-governance has been generally agreed upon by the global community and this has become a paramount issue in developing countries. The applications of eGovernance require research prior to large scale implementation and academia can play a vital role in the research. Borrowing from the academic model of study review and peer review publication in all studies sponsored by industry and government, would bring about a great deal of more research. Further, publication on this topic is needed in order to bring about a more permanent, institutional, and transparent process that will not only ensure shared knowledge and accelerated development amongst the global e-

governance community, but also uphold the virtues in the applications resulting from the improved research standards.

References

1. Sims J.M. (2008) An introduction to institutional review boards. Dimensions of Critical Care Nursing. Sep-Oct;27(5):223-5.
2. Review Boards. Applied Social Research Methods Series, vol. 31. Newbury Park, CA: Sage Publications, 1992.
3. Institutional Review Boards: Their Role in Reviewing Approved Research, Office of Inspector General, HHS. Available at: http://www.oig.hhs.gov/oei/reports/oei-01-97-00190.pdf
4. Ray S, Mukherjee A. (2007) Development of a framework towards successful implementation of e-governance initiatives in health sector in India. International Journal of Health Care Quality Assurance. 20(6):464-83.
5. Kluge E.H.(2008) Ethical aspects of future health care: globalisation of markets and differentiation of societies - ethical challenges. Studies in Health Technology and Informatics. 134:77-87.
6. N. Black, S. vanRooyen, F. Godlee, R. Smith, S. Evans (1998) What makes a good reviewer and a good review for a general medical journal? Journal of the American Medical Association 280: 231-233
7. The International Congress on Biomedical Peer Review and Global Communications Advisory Board, Congress on Biomedical Peer Review. Journal of the American Medical Association 280: 213-302, 1998.
8. Ethics of Peer Review: A Guide for Manuscript Reviewers, Sara Rockwell, Ph.D. Departments of Therapeutic Radiology and Pharmacology, and Office of Scientific Affairs, Yale University School of Medicine. Available at: http://radonc.yale.edu/pdf/Ethical_Issues_in_Peer_Review.pdf
9. Markman JR., Markman M. Running an ethical trial 60 years after the Nuremberg Code. The Lancet Oncology. 2007 Dec;8(12):1139-46.
10. Twenty Years After: The Legacy of the Tuskegee Syphilis Study. The Hastings Center Report 22 (No. 6, November/December 1992): 29-40. Includes articles by Arthur L. Caplan, Harold Edgar, Patricia A. King, and James H. Jones.
11. Marshall, Ernest. "Does the Moral Philosophy of the Belmont Report Rest on a Mistake?" IRB 8 (No. 6, November/December 1986): 5-6
12. Peters DH, Muraleedharan VR.(2008) Regulating India's health services: to what end? What future? Social Science and Medicine. 66(10):2133-44.
13. Dreezen I. Telemedicine and informed consent. Medicine and Law. 2004; 23(3): 541 - 549
14. Stanberry B. Legal and ethical aspects of telemedicine. Journal of telemedicine and telecare. 2006; 12: 166 – 175
15. Assessment of Approaches to Evaluating Telemedicine. Lewin Group Report. 2000 Prepared for: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. Available at: http://aspe.hhs.gov/health/reports/AAET/aaet.htm
16. Brahams D. The medico-legal implications of teleconsulting in the UK. J Telemed Telecare 1995;1:196-201
17. Sieber, Joan E. Planning Ethically Responsible Research: A Guide for Students and Internal
18. Assessment of Approaches to Evaluating Telemedicine. Lewin Group Report. 2000 Prepared for: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services
19. Rob M. Peters, Marijn Janssen, Tom M. van Engers, (2004) Measuring e-Government Impact: Existing practices and shortcomings, Proceedings of the 7th International Conference on Electronic Commerce, ICEC05
20. Bhatnagar S., Rama Rao T.P., Singh N., Vaidya R. , Mandal M. (2007) Impact Assessment Study, Center for e-Governance, Indian Institute of Management, Ahmedabad. Available at: http://www.iimahd.ernet.in/egov/documents/impact-assessment-study-dit.pdf
21. Bhatnagar, S. Building Trust through e-Government: Leadership and Managerial Issues. Ahmedabad: Indian Institute of Management.. Available at: www.iimahd.ernet.in/~subhash/pdfs/CHRIDraftPaper2003.pdf
22. UN egovernment Survey 2008. From E; Government to Connected Governance. Available at: http://unpan1.un.org/intradoc/groups/public/documents/UN/UNPAN028607.pdf
23. Guidelines for Capacity Building and Institutional Framework for e-Governance under NeGP. Available at: http://mit.gov.in/download/Capacity%20Building%20Guidelines-21st%20March,%2005.pdf
24. Brandt M.L. Stanford Report: IRB burden studied in cost analysis. Available at http://news-service.stanford.edu/news/2003/august6/humphreys.html Accessed at 29/11/1008

25. Wagner T. H., Bhandari A., Chadwick G.L., Nelson D. K. (2003) The cost of operating institutional review boards (IRBs). Acad Med. 2003 Jun ;78 (6):638-44
26. Humphreys K., Trafton J., Wagner T. H., (2003) The Cost of Institutional Review Board Procedures in Multicenter Observational Research. Annals of internal medicine. 139 (1): 77
27. Report of the Research Councils UK Efficiency and Effectiveness of Peer Review Project.(2006) Available at: http://www.rcuk.ac.uk/cmsweb/downloads/rcuk/documents/rcukprreport.pdf
28. Jones S., Irani Z., Sharif A. (2007) E-Government Evaluation: Reflections On Three Organisational Case Studies, SBN ~ ISSN:1530-1605
29. UNDP-Cisco Strategic Partnership on e-Governance. Available at: http://sdnhq.undp.org/e-gov/undp-cisco-egov.html. Accessed on 29/11/2008
30. Löfstedt U.(2005) Assessment Of Current Research And Some Proposals For Future Directions. International Journal of Public Information Systems, vol 2005:1
31. Rama Rao T. P., Venkata Rao V., Bhatnagar S. C., Satyanarayana J. (2004) E-Governance Assessment Frameworks. Availbale at: http://mit.gov.in/download/NISG_EAF_18-05-04.pdf
32. Chircu A. M.(2008) E-government evaluation: towards a multidimensional framework. Electronic Government, an International Journal 2008 - Vol. 5, No.4 pp. 345 – 363
33. Liu, L. (2006) Evaluations on China E-Government from International Organizations, in: China EGovernment Development Report, C. Wang, X. Zhang and S. Yu (eds.), Social Sciences Academic Press, Beijing, 2006, pp. 19-30.
34. Špaček, D, Malý I.(2008). E -Government evaluation and its practice in the Czech Republic: challenges of synergies?. In Public Policy and Administration: Challenges and Syntergies - Presented papers from the 16th NISPAcee Annual Conference. Bratislava : NISPAcee, 2008. ISBN 978 -80 -89013 -38 -8, pp. 1 -17. 15.5.
35. Advisory Committee on Human Radiation Experiments, Final Report, Washington, D.C.: U.S. Government Printing Office, 1995.
36. The Peer Review Process: A Report to the JISC Scholarly Communications Group, Fytton Rowland, Department of Information Science, Loughborough University

About the Author

Stan Kachnowski is a leading scholar, educator and researcher in the field of healthcare technology management. He has taught e-health and healthcare e-business for the past 18 years and authored or co-authored over 120 scholarly works and presentations for the world's leading medical societies and organizations. Over the past three years he has taught classes onsite and remotely as a visiting professor at the Indian Institute of Technology Delhi, India and served as the Chair for the Healthcare Innovation Technology Lab, USA. Prof. Kachnowski is also a fellow of England's Royal Society of Medicine.