Croatian Medical Journal Introduces Culture, Control, and the Study of Research Integrity

Mladen Petrovečki, Mary D. Scheetz*

Department of Computer Science, Rijeka University School of Medicine, Rijeka, and Dubrava University Hospital, Zagreb, Croatia; and Office of Research Integrity, Division of Education and Integrity, Department of Health and Human Services, Rockville (MD), USA

Culture, control, and the study of research integrity represent the future goals of the Croatian Medical Journal. This article will highlight research integrity as experienced in the USA by the Office of Research Integrity (ORI) and discuss the framework being developed in Croatia. First, the Croatian Medical Journal seeks to promote a research culture that is aware of research integrity. This will be accomplished through the education and training of Croatian researchers interested in publishing their results in international scientific journals. To facilitate this goal, the Croatian Medical Journal introduces, what it believes to be, the first Research Integrity Editor. Second, the Croatian Medical Journal intends to facilitate the development of an Office of Research Integrity based on ORI model. The Croatian office of research integrity would be authorized to develop regulations to define scientific misconduct, investigate, and develop administrative actions against those found to have committed scientific misconduct. Furthermore, the office would be responsible for developing national education standards for promoting research integrity and the responsible conduct of research. Third, the Croatian Medical Journal is developing a science-based research agenda. This new research agenda will examine topics similar to those presented recently at the first Research Conference on Research Integrity held in Bethesda, Maryland, USA (November, 2000). The initial research topics would include studying those variables and mechanisms that help to promote research integrity and honorable research practices. This Editorial represents the first step towards achieving this goals, by establishing a collaborative relationship between ORI and the Croatian Medical Journal.

Key words: Croatia; education, medical; ethics, medical; misconduct, scientific; ownership; peer review; research; publishing; United States Office of Research Integrity

Scientific problems often produce reasonable questions; such is the nature of science. The questions cannot always be answered. Science is not about quick answers, but rather about seeking the truth. So as the new millennium begins, so do new problems, new debates, and in the spirit of progress, new solutions. The Croatian Medical Journal seeks to be a leader in addressing issues related to research integrity as it applies to biomedical publishing.

It is assumed that scientists are part of a profession aware of and committed to demonstrating a shared set of values about the importance of empirical and objective research. At the same time it is commonly held that scientists share a common understanding of how research is conducted; that they understand the importance of the responsible conduct of research and possess knowledge about appropriate research design, analysis, and reporting research results (1). However, cases of scientific misconduct and questionable research practices in recent years indicate that “seeking the truth” isn’t as commonly a shared value as once thought.

Good science requires good research. It also requires a fundamental understanding of the basic principles and ethos of the scientific culture. The contemporary research environment in the biomedical sciences at the turn of the millennium represents a research enterprise much different from the scientific culture of previous decades. A variety of factors have contributed to this evolution: 1) increased costs for research due to sophisticated instruments; 2) the size and number of major research centers focusing on single-disease or single tech-
tology programs; 3) the growth of collaborative research; and 4) the specialization of research laboratories. The continuing advances made in information technology have also enabled researchers to collaborate cross-culturally and at increasing speeds. Yet, “the same technology that makes life easier for the honest researcher may also assist the dishonest one. Rapid and easy dissemination will facilitate plagiarism, the fabrication of data (including databases), and attempts to obscure authorship or authenticity. In addition, the increased use of computers to mechanize team written reports may influence how teams assign and accept responsibility for the integrity and accuracy of the entire text” (2).

Despite the progress made on a variety of research fronts, patience, honesty, and meticulous attention to detail have sometimes been forgotten in the hurry to be the “first” — whether it be the first patent, discovery, or published author. Thus, the challenge for ensuring the research integrity and the quality of publications increases as the technology of managing and transmitting information improves. These technological advances have produced research integrity challenges not previously addressed by the research community (3).

The Croatian Medical Journal was born at a time when it was critical to address the needs of its medical and health care professionals dealing with the tragedies of war (4). That time has passed and the journal has evolved into the premier leader of peer-reviewed, biomedical research in Croatia. The Journal is now poised to address some of the contemporary issues related to the responsible conduct of research and research integrity. The new assignment of a research integrity editor will help to promote this timely cause.

What is Research Integrity?

Research integrity has yet to be formally defined. Searching the term “research integrity” via the National Library of Medicine, Medical Subject Heading (MeSH) cross references the term with “scientific misconduct”, “research”, and the “United States Office of Research Integrity”. Searching “research integrity” through the Medline using Ovid web-based system at the Rudjer Boskovic Institute (Zagreb, Croatia), cross references “research integrity” with the terms “research personnel” and “ethics”. In Croatian the term is summarized as “znanstvenoistraživačka čestitost” (M. Marušić, 2000).

If “integrity” is defined as being honest in dealings with others (5), then research integrity could be defined as researchers being honest with each other, as well as exercising honorable research practices that are endorsed by the research community. These research practices cover a broad range, beginning with the inception of the research idea, continuing through collaboration with colleagues during the stage of experiment testing, and finally culminating with the publication process.

Research integrity is not to be confused with research ethics. These two terms share some commonality, yet the main difference lies in substance: research ethics usually pertains to issues related to the decisions about, or treatment practices of, humans in research. Research integrity deals with the question of truth and honesty in science, as well as complying with commonly accepted research practices beholden to the scientific community.

What is Research Misconduct?

In the United States, research misconduct is defined as “fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data” (6). This definition has served as the benchmark for many decisions and discussions about scientific misconduct. However, other definitions also exist. The Danish Committee on Scientific Dishonesty, a national committee covering the health sciences, defines scientific misconduct as “deceptive acts, serious enough to falsify or distort the scientific message and/or to give false credit or emphasis to a scientist” (7). Research misconduct has yet to be defined in Croatia. As a new country, it is in a unique position to consider definitions from a variety of countries, but also has to endure the growing pains of identifying research misconduct as well.

Although debate continues over the definition, cases of scientific misconduct continue to stimulate a variety of dialogues in academic and professional circles. It encompasses a wide range of issues that may potentially affect various groups throughout society. Those affected include, but are not limited to: funding agencies, scientists, journal editors, university administrators, and the general public who trust their health care to practitioners whose opinions, based on current research, impart information to a newly trained professional.

There is potential for a research misconduct allegation to have a high impact on all of the individuals involved as well as the institution where the alleged misconduct occurred. Factors such as the scope of the misconduct, the length of time the misconduct went undetected, the prestige of the individuals or institutions involved, the possible impact on public health or clinical treatment, retaliation against the complainant, other mishandling of the allegation, and the extent of media coverage can all play a role in the impact that a particular case may have on individual researchers or their institutions (8).

If research misconduct goes undetected and emerges in the literature, there may be a serious effect on the consumer of the information, and possibly on the reputation of the journal. The severity of misconduct in science, whether taking the form of plagiarism, misconduct, or data fabrication, may hinder the publisher’s reputation, and produce a negative economic outcome. Because of this possible threat, journal editors and those in the publishing industry are in a unique position to promote research integrity through developing and enforcing policies that promote research integrity and the responsible conduct of research.

Office of Research Integrity

The Office of Research Integrity (ORI), established in June, 1992, promotes integrity in biomedical and behavioral research supported by the Public Health Service and involves about 4,000 institutions worldwide. In fis-
cultural year 2000, the Public Health Service provided more than US$12 billion to support biomedical and behavioral research in extramural and intramural programs. (Extramural programs provide funding to research institutions that are not part of the Federal government – medical schools, universities, colleges, hospitals, research institutes. Intramural programs provide funding for research conducted within Federal government facilities.) Organizational, ORI is located in the Office of Public Health and Science within the Office of the Secretary of Health and Human Services.

The Office of Research Integrity carries out its responsibility by: (a) developing policies, procedures and regulations related to the detection, investigation and prevention of research misconduct, and the responsible conduct of research; (b) reviewing reports of 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); (c) recommending research misconduct findings and administrative actions to the Assistant Secretary for Health for decision, subject to appeal; (d) 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; (e) conducting policy analyses, evaluations and research to build the knowledge base in research misconduct, research integrity, and prevention and to improve Health and Human Services research integrity policies and procedures; (f) assisting the Office of General Counsel (OGC) to present cases before the Health and Human Services Departmental Appeals Board; (g) administering programs for: maintaining institutional assurances, responding to allegations of retaliation against whistleblowers, approving intramural and extramural policies and procedures, and (h) responding to Freedom of Information Act and Privacy Act requests.

Case Statistics
Since its inception in 1992, the Office of Research Integrity has made over 100 findings of scientific misconduct. The findings have resulted in a variety of administrative actions, and have resulted in over 85 corrections to the literature either through corrections or retractions to text, data, or figures in entire articles. The number of scientific misconduct cases for 2000 are highlighted in Table 1.

The research community has become more adept and assertive at addressing allegations of scientific misconduct during the past decade. Yet historically, the Office of Research Integrity has made a finding of misconduct in about one-third of its cases.

Research Integrity Education and Outreach
In addition to addressing allegations of research misconduct, the Office of Research Integrity has extensive education and outreach programs to promote research integrity. Seventeen conferences have been held or co-sponsored with professional societies nationwide since 1993. Conference topics included: Introductory Workshop for Institutional Misconduct Officials; Managing Biomedical Research Laboratories, Authorship in Biomedical Publications; The Role and Activities of Scientific Societies in Promoting Research Integrity; Responding to Allegations of Research Misconduct Inquiry, Investigations, and Outcomes: A Practicum. Additional conferences continue to be scheduled for 2001 addressing the following issues: Promoting Research Integrity in Communication Sciences and Disorders and Related Disciplines; Research Compliance: Challenges and Opportunities; Educating for the Responsible Conduct of Research in the New Millennium; and Legal Issues and Strategies in Responding to Research Misconduct Allegations.

ORI is developing guidelines for handling misconduct and research integrity issues. Guideline topics which are under development include: (a) Guidelines for the Responsible Whistleblowing; (b) Guidelines for Respondents Accused of Misconduct in Science; and (c) Guidelines for Institutions Investigating Allegations of Possible Misconduct in Clinical Research. The Guidelines for Journal Editors for Addressing Allegations of Scientific Misconduct is available and has been widely disseminated to journal editors and publishing professionals as a resource guide. The Office of Research Integrity also publishes a quarterly newsletter that is distributed to over 3,500 readers. The newsletter and other Office of Research Integrity publications and documents are available on the Office of Research Integrity website http://ori.dhhs.gov.

Research Program
Since its establishment the Office of Research Integrity has worked to promote research integrity through conducting studies and developing guidelines for the research community. These efforts have been done in an attempt to develop a knowledge base on important issues, such as the impact of misconduct allegations on exonerated scientists, the experience of whistleblowers in the aftermath of making allegations, the research guidelines adopted by medical schools, and the cases of research misconduct. In addition, with the realization that a more comprehensive coordinated effort with scholars was needed in order to develop the scientific base on research integrity issues, the Office of Research Integrity developed the first Research Conference on Research Integrity.

Research Conference on Research Integrity
More than 220 researchers, doctoral candidates, graduate students, and administrators including participants from Germany, Great Britain, Japan, Brazil, Denmark, Israel, and Croatia, attended the first research conference on research integrity in Bethesda, Maryland, November 19-20, 2000.
2000 (Fig. 1). The conference was co-chaired by Drs. Nicholas Steneck from the University of Michigan and Mary Scheetz from the Office of Research Integrity. The conference was sponsored by ORI and co-sponsored by the National Institutes of Health, the National Science Foundation, the Association of American Medical Colleges, and the American Association for the Advancement of Science.

The goal of the research conference was to provide a forum for scholarly debate and to encourage research on the sociological, psychological, educational, institutional, organizational, and cultural factors that positively or negatively influence integrity in research. The conference was held as the first step toward developing a science-based understanding of the research process that will lead to improved strategies for promoting and maintaining research integrity.

Research topics presented at the conference included:

- interviews with scientists against whom misconduct findings have been made,
- an ethnographic study of the relationships between scientific practices,
- research accountability and the use of records and record keeping in a lab,
- a content analysis of instruction to authors in journals,
- trend analysis of conflicts of interest,
- a survey of attitudes toward data editing,
- an experiment involving informed consent,
- field investigations into organizational influences on scientific integrity,
- a developmental study of professional identities in doctoral candidates,
- the evaluation of education programs in the responsible conduct of research.

One of the greatest accomplishments of the first Research Conference on Research Integrity was its cross-disciplinary nature. Scholars from various academic disciplines met for the first time at this conference and shared enthusiasm over the prospects of future collaborations. Just as research integrity is a multi-faceted issue, addressing and solving problems associated with research integrity will be best served from a multi-disciplinary approach. The research papers delivered at the research conference represent an array of research integrity topics. Conference proceedings will be posted on the ORI web site when completed and selected papers will be submitted to a peer reviewed journal for publication. Conference attendees overwhelmingly support the idea of future research conferences on research integrity. ORI looks forward to a future research conference in November, 2002.

**ORI Research Grant Program**

To promote empirical research on research integrity, a new research grant program was recently initiated. The Office of Research Integrity together with the National Institute of Neurological Disorders and Stroke (NINDS) announced the first grant program specifically aimed at funding research on research integrity in August, 2000. Research integrity in this context is understood as “adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms” related to research. The grant program was designed to foster research on the institutions, processes, and values that positively and/or negatively influence integrity in research. The sponsors are particularly interested in studies that will inform policymakers and research institutions on effective ways to foster integrity in publicly-funded research programs.

Little is known about the causes, significance of, or remedies for practices that fall short of professional standards of research conduct. There is little empirical evidence to determine whether intentional research misconduct is rare or widespread. Therefore, proposals were encouraged that would provide data that could be generalized about the ways researchers and research institutions meet, or fail to meet, their professional responsibilities in the conduct, evaluation, and reporting of research. For this grant program, “research” is defined broadly to include societal, institutional, and individual aspects of the enterprise.

Response to the grant program has been well received, indicating an interest in the research associated with research integrity. Grant awards are merit-based, and it is hoped that the first round of research grants awarded will develop a science-based understanding of the research process that will lead to improved strategies for understanding the diverse issues associated with research integrity.

**Research Integrity in Croatia**

Research integrity and scientific misconduct issues in Croatia exist in proportion, and in their nature, to those in the United States. The pressures for publishing and the competition for resources are also commonplace. Yet, Croatia has been actively teaching topics related to the responsible conduct in research since 1996. Second year medical students in all four of Croatia’s University Medical Schools (Osijek, Split, Rijeka, and Zagreb) are taught and tested on a curriculum that includes The Introduction to Scientific Research. Students preparing to receive a PhD in Medical Sciences are taught and tested on a curriculum that includes Structure, Methods, and Function of Scientific Research. These lectures and

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**Figure 1.** Announcement for the First Conference on Research Integrity
seminars provide students with an understanding of what is involved with research along with the medical, ethical, and statistical rules. They learn how to design and carry out a research proposal as well as how to read and write a scientific paper. Beginning in March, 2001, additional hours of instruction will include the topics of research integrity and scientific misconduct. This curriculum provides students with the necessary tools for appreciating and implementing many of the subjects related to the responsible conduct of research.

Croatia’s geographic size presents a challenging set of problems when research misconduct is alleged. The research community is much smaller than that of the United States, therefore it is sometimes difficult to keep the allegations confidential. Because Croatia does not currently have a system in place to address or monitor scientific misconduct allegations, conducting inquiries or investigations can be complicated. Geographic size cannot be an excuse for ignoring allegations of scientific misconduct, especially when resources are in sharp demand and public health is at stake. Because these concerns are important to the government, a revised Higher Education Act for the Republic of Croatia is currently underway (11).

Editors of the Croatian Medical Journal have been instrumental in developing the revised Higher Education Act (11). The newly written Article 40 from the Act defines that “1) The Senate or the Professional Council respectively appoints the Ethics Board which promotes ethical standards in performing the activity of the institution of higher education and the work of teachers, scientists and associates; 2) The Ethics Board consists of five members; three are representatives of the institution of higher education and two are distinguished public persons outside the institution of higher education; and 3) The Ethics Board of an institution of higher education: (a) expresses its opinions about the ethics of conducting research on people, animals and the environment which is performed for the requirements of teaching, scientific research, and professional work; (b) evaluates the authenticity of professional and scientific papers and theses; (c) initiates the procedure for revoking master’s or doctoral degrees when necessary; (d) submits to the rector or the dean respectively, proposals for termination of employment for those persons who have violated ethical principles in their work, and; (e) addresses other ethical issues as determined by the statute or the by-laws of the institution of higher education” (11). Although this Act primarily addresses research ethics, this revised Act will help to regulate possible misconduct, as noted above in subpart (d).

The Croatian Medical Journal Editorial Board is credited for initiating this dialogue with the Ministry of Science, based in part on research integrity concerns addressed in the international community. Once formally codified, the implementation of these regulations will be strictly enforced.

Croatian Medical Journal and Research Integrity

The Croatian Medical Journal became the first Croatian biomedical journal to be indexed in MEDLINE (1998) and in Current Contents/Clinical Medicine (1999). It has earned the reputation of being the leading biomedical journal in Croatia and joins the ranks of credible peer-reviewed journals in the international biomedical arena. It has contributed to the building of a particular “bridge” between the scientific periphery and mainstream science (East/South vs. West/North, ref. 12). Its acclaim has made it a journal that has gained notoriety, and as a result, the journal is able to be more selective of the manuscripts it publishes.

Along with this honor, is the responsibility of serving the readership. Journals play a critical role by educating readers about the responsible conduct of research and promoting research integrity by publishing standards of acceptable research practices. One of the Croatian Medical Journal’s primary missions is the continuing education of its readers and authors. In addition to assisting authors with presentation, writing, and editing for language and style, the journal will enhance its role by providing a research integrity editor (13). The Croatian Medical Journal is the first international biomedical journal with a research integrity editor who is a member of the Editorial Board. Among the many responsibilities held by the research integrity editor, is the responsibility for reviewing questionable research and publication practices detected in manuscripts.

Despite healthy publication growth and an increase in circulation, the Journal has not been without problems. The Croatian Medical Journal, like other biomedical journals, has been afflicted with scientific misconduct problems such as authorship disputes, duplicate publication, and data falsification, to name a few. In one particular case, where falsification was found, the Croatian Medical Journal imposed a financial penalty on the author to pay for the reviewer’s time and time spent on correspondences. In another situation, the author was told not to submit any future manuscripts to Croatian Medical Journal for publication consideration due to the detection of scientific misconduct in the manuscript. For the Croatian Medical Journal, the new research integrity editor will perform duties such as, detecting and investigating possible misconduct that surfaces in manuscripts submitted for publication consideration. The research integrity editor will be responsible for monitoring and investigating these problems and proposing disciplinary actions to the Editors-in-Chief, as necessary.

Questions surrounding a manuscript are not automatically labeled as “scientific misconduct”. Honest error does occur and the Croatian Medical Journal has worked with authors to address issues surrounding research design and statistics. However, the Journal recognizes that there are points along the research continuum when discrepancies can arise. These occur in the form of authorship disputes, or when reviewers or editors detect possible scientific misconduct. The research integrity editor will be responsible for managing these types of issues, contact the proper authorities, and make the necessary recommendations to the Editor-in-Chief when appropriate.

Croatian Medical Journal – Looking Ahead

Since its inception, the main goals of the Croatian Medical Journal have not changed; but they will be enhanced by addressing scientific misconduct, research integrity, and the responsible conduct of research under the auspices of the research integrity editor. Manuscripts sub-
ommited for publication consideration will continue to go through a rigorous peer-review process but as previously noted, any manuscript suspect of scientific misconduct will receive immediate attention and a special review.

In addition to being responsible for overseeing and protecting the integrity of the Croatian Medical Journal, the research integrity editor will also be conducting research in the area of the responsible conduct of research. The development of the research agenda is currently underway, but some of the topics being considered include: retrospective and prospective studies of papers submitted and published in Croatian Medical Journal; cross-cultural publication practices; and the deviant behavior of scientists. The goals of the proposed research are to identify appropriate mechanisms for promoting honorable research practices, and to have data that will provide the basis for decision-making when a disciplinary action is to be applied to those who do not comply with responsible research practices. The research will hopefully provide data to serve both the publishing and research integrity communities.

The Croatian Medical Journal is committed to addressing allegations of research misconduct that surface within the journal’s jurisdiction. As a journal that publishes authors from around the world (approximately 70% of the published manuscripts are from authors outside of Croatia), the Croatian Medical Journal is acutely aware of the instances and ramifications of scientific misconduct and therefore, the importance of promoting research integrity and the responsible conduct of research. Unfortunately, there is not a central authority in Croatia responsible for overseeing research integrity and handling allegations of scientific misconduct at this time. However, Croatia is fortunate to look to models used in various countries for addressing research misconduct and promoting research integrity. Careful study of oversight and regulatory systems used in various countries for addressing scientific misconduct will provide options for implementing an appropriate system for the Croatian biomedical research community.

Ideally, Croatia will establish an office similar to the Office of Research Integrity. Such an office will handle allegations of scientific misconduct, promote research integrity through education, and also conduct research. The plan is to have the office affiliated with the Department of Computer Science at the Rijeka University School of Medicine. The preparations for this office are currently underway.

Concluding Remarks

Formulating norms and recommendations for good scientific practice only lays a foundation for their effect in real life. The difficulties in observing basic principles usually arise in their implementation. The Croatian Medical Journal seeks to address research integrity issues with a critical eye; honoring the scientific tradition of honesty, integrity and beneficence.

With the addition of a research integrity editor, and this collaboration with the Office of Research Integrity, it is hoped that at least three points are made: 1) Croatian Medical Journal with the Office at the Rijeka University School of Medicine (currently underway) is starting to promote the culture of research integrity in Croatia, as already recognized internationally; 2) that the Research Integrity Editor, Editors-in-Chief, the Croatian Medical Journal Editorial Board, and reviewers will address scientific misconduct issues immediately as they appear during the publication process and; 3) begin developing a research agenda to examine scientific misconduct as it pertains to publication practices, and other research topics addressed at the recent Research Conference on Research Integrity in Bethesda.

This paper represents the first step towards achieving these goals. Such collaborations provide an opportunity to learn, exchange concerns, and share experiences about a topic, that by today’s standards, is borderless. The Croatian Medical Journal is committed to working with the larger research community in preventing scientific misconduct and promoting the responsible conduct of research.

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References

6. 42 C.F.R. Part 50, Subpart A.

Correspondence to:
Mladen Petrovečki
Department of Computer Science

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The program will include 5-7 lectures by invited speakers – experts of international recognition, 40-45 paper presentations, live tele-surgery (a surgery performed in Mostar, Bosnia and Herzegovina, or in Greece), and project and product exhibition.

**Medical Specialties** include, but are not limited to: ENT, radiology, endoscopy, minimally invasive surgery, and craniofacial surgery.

**Congress Topics:** Endoscopic surgery Telesurgery Computer science, biomechanics, and electrical engineering, including: computer-assisted radiology (CAR) and surgery (CAS) Medical image processing and analysis Picture archiving and communication systems Computer programs for 3D-CT/MRI imaging Computer-assisted diagnosis, surgical planning, and postoperative analysis Computer applications in ENT, orthopedics, neurosurgery, plastic and reconstructive surgery, and thoracoabdominal surgery Image-guided surgery and therapy Surgical training Virtual reality telemedicine: Telepathology, Teleradiology, Telesurgery/Tele-CA-FESS, Tele-video conferences.

**Contact:**
Dr Ivica Klapan, ENT Department, Division of Plastic and Reconstructive Head and Neck Surgery and Rhinosurgery, Zagreb University School of Medicine and Zagreb Hospital Center, Šalata 4, 10000 Zagreb, Croatia