The Battlefield Health and Trauma Research Institute Scientific Ethics Committee: An evolving model for fostering a culture of integrity

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> "The scientific enterprise is built on a foundation of trust. Society trusts that scientific research results are an honest and accurate reflection of a researcher's work. Researchers equally trust that their colleagues have gathered data carefully, have used appropriate analytic and statistical techniques, have reported their results accurately, and have treated the work of other researchers with respect. When this trust is misplaced and the professional standards of science are violated, researchers are not just personally affronted—they feel that the base of their profession has been undermined. This would impact the relationship between science and society."

This quotation is the opening paragraph of a guidebook published by the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine and eloquently depicts the central role that trust has in scientific investigation.[1] Yet, newspapers periodically report instances in which scientists have acted unethically in their scientific practices. To cite a few recent examples: Joachim Boldt, a presumed leader in surgical resuscitation, is currently under investigation for fabrication of published scientific studies[2] and performing research without Institutional Review Board approval.[3] An investigation at Walter Reed Army Medical Center determined that Timothy Kuklo, an Army orthopedic surgeon, claimed other doctors as coauthors on an article, forging their signatures on submission forms, and may have overstated benefits of a product of a company for which he acted as a paid consultant.[4] The article that launched the concern that the measles, mumps, and rubella vaccine causes autism has recently been retracted by the editors of the noted British journal *The Lancet*[5] following findings of fraudulent activity by the principal investigator, Andrew Wakefield.[6] In a 2005 ruling by the Office of Research Integrity (ORI), Eric Poehlman, PhD, was found to have published fabricated research in 10 articles and submitted fraudulent findings in National Institutes of Health (NIH) grant applications;[7] because the latter is a federal criminal offense, he was sentenced to 1 year and 1 day imprisonment followed by 2 years of supervised release and fined $100.[8] In addition, Poehlman agreed to pay almost $200,000 for claims brought by the US Attorney General's Office and attorneys' fees and also agreed to be permanently barred from seeking federal grants and contracts.[8]

The ORI defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."[9] Although the previous examples are well publicized, recent surveys of scientists suggest that the prevalence of fabrication, falsification, or plagiarism (FFP) is only 1% to 2%, based on self-reporting.[10,11] However, approximately 33% of scientists admitted to using questionable research practices (e.g., failing to present data that contradict one's previous research or hypothesis, "cleaning" data, etc.).[10,11] When scientists were asked if they had personal knowledge of a colleague who misused data, the average percentages of FFP rose to 14% and of questionable research practices increased up to 72% (dependent on the research practice inquired of).[10] Clearly, a problem exists. The existence of this problem pollutes the scientific literature, risks damage to the integrity of the entire research enterprise, and may produce harm in patients who are treated with products of tainted research.

The pressures on individuals pursuing scientific research continue to grow. These may include pressure to publish, as exemplified by the old axiom "publish or perish;" the need to secure research funding, particularly in the current environment of reduced funding availability; career promotion and advancement; the desire to be the first to find a discovery; and competition with others. For researchers within any Department of Defense (DoD) laboratory, the military hierarchy may place further demands on individuals because lower-ranking scientists may feel pressure, either stated or implied, to comply with the requests of superior officers (e.g., to provide "gift authorship" to a superior officer). In both military and civilian institutions, physicians, nurses, and other clinicians may be placed in a position in which research is encouraged or required, despite the fact that they have often received no formal training in experimental design, statistics, and responsible conduct of research (RCR). Indeed, recent surveys indicate higher rates of misconduct reporting among clinical, medical, and pharmacologic researchers than those of surveys of biomedical researchers or those in other fields;[10] contributing factors to this phenomenon may include the lack of formal

KEY WORDS: Responsible conduct of research; ethics.

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DOI: 10.1097/TA.0b013e3182605f9e

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
01 AUG 2012	**N/A**	**-**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
The Battlefield Health and Trauma Research Institute Scientific Ethics Committee: An evolving model for fostering a culture of integrity	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)	5d. PROJECT NUMBER
Ryan K. L., Blackbourne L. H., Cancio L. C., Dunn W. J., Jordan B. S., McClinton A. R., Nelson B. S., Rathbone C. R., Ross J. D., Kragh Jr. J. F.,	5e. TASK NUMBER
	5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT NUMBER
United States Army Institute of Surgical Research, JBSA Fort Sam Houston, TX	

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**UU**	**4**	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std Z39-18

research training and placing the welfare of the patient above the pursuit of scientific truth.[12] In addition to ethical performance of experiments and treatment of data, researchers must also be aware of and comply with regulations governing the ethical use of human and animal research subjects. Furthermore, researchers must be cognizant of potential conflict of interest issues and other influences that might threaten their ability to objectively perform the research (e.g., funding for research provided by a company, honoraria, etc.). How does an investigator successfully navigate this ethical landscape? Are there mechanisms in place to provide investigators training and guidance?

THE ACADEMIC MODEL

Just as regulations governing the ethical use of human and animal research subjects grew from past transgressions, new practices for RCR have arisen from a number of high profile cases of misconduct in the late 1970s and early 1980s (see Broad and Wade[13]). In response, the Department of Health and Human Services established the Office of Scientific Integrity in 1989 within NIH. However, complaints surfaced immediately that this constituted a conflict of interest because NIH was funding research and was now also responsible for investigating scientific misconduct. In response, the ORI was established in 1992 within the Office of the Assistant Secretary of Health, which is outside of the NIH.[9] The ORI is responsible for investigating allegations of scientific misconduct involving research conducted or supported by components of the Public Health Service (PHS), to include NIH, and for punishing individuals found to have committed scientific misconduct.[9] The ORI promulgates requirements for institutions receiving funding from PHS sources to have institutional policies and procedures for investigations of allegations of scientific misconduct. As examples, these policies and regulations require institutions to appoint Research Integrity Officers and other institutional officials responsible for objective and fair investigation of allegations using specified procedures that protect both the whistleblower and the individual alleged to have committed misconduct.[9] Furthermore, federal regulations now require training in RCR for individuals receiving NIH training grants and career development awards.[14] RCR includes training on such topics as data management, conflict of interest, protection of human subjects, animal welfare, research misconduct, and publication and authorship; moreover, there are a variety of training resources available[15,16]. In addition, the ORI has provided training videos (“The Lab”) as well as online information and case reports (http://ori.hhs.gov/). Although this is a brief and very incomplete recitation of the academic model, the model is based on investigation of scientific misconduct issues and training to obviate such issues before they occur.

THE BATTLEFIELD HEALTH AND TRAUMA RESEARCH INSTITUTE MODEL

ORI initiatives do not necessarily translate to DoD laboratories, as many do not receive PHS funding. As an example, although there is a clear requirement for integrity in the performance of research (DoD Instruction 3210.7), there is no current DoD requirement for training in RCR or for the appointment of an institutional Research Integrity Officer. In this codification of the means to deal with issues of scientific misconduct, the DoD is lagging behind the civilian research community. DoD investigators engaged in research involving either animal or human subjects are required to be trained in ethical issues related to animal or human research; Battlefield Health and Trauma Research Institute (BHTRI) investigators receive online training in these ethical issues using resources provided by the Collaborative Institutional Training Initiative. However, BHTRI investigators comprise a diverse population of individuals, from those formally trained in research practices (e.g., PhD level investigators) to those who may have received little or no training in research (e.g., clinical staff).

Recognizing the need for training and education in best practices for the performance of ethical research, a scientific ethics committee was established at the US Army Institute of Surgical Research early in 2010. To be fully transparent, there were several ongoing investigations of scientific activities at the time the committee was established. The establishment of this committee therefore occurred at the local level rather than being dictated by external regulation, with the intent that increased awareness of standards of ethical conduct would lead to avoidance of potential issues. Later in 2010, US Navy and Air Force units were moved to Fort Sam Houston, and the BHTRI was established as a triservice facility. With command support from each service branch, the committee expanded to include representation from the Navy and Air Force units and was renamed the BHTRI Scientific Ethics Committee. The mission of this committee is to promote a climate of scientific integrity by providing training and guidance for the performance of research that conforms to the highest ethical standards of the research enterprise. Our purpose was to serve as advisors to the BHTRI commanders and scientists regarding the responsible and ethical conduct of research. Our model is therefore one of providing guidance and assistance to individuals with questions concerning research ethics, rather than being concerned with investigating misconduct (i.e., “chaplains” vs. “policemen”). The committee is composed of working scientists from most of the research units within the BHTRI, along with the Institutional Review Board and Institutional Animal Care and Use Committee administrators. Members are purposefully drawn from within the ranks of different research units in the hope that investigators will feel comfortable asking potentially sensitive questions to someone they know and trust. To further this end, the membership is made up of individuals with diverse training (i.e., MD, RN, PhD) and background, differing employment status (military, civilian DoD employees, and contractors), age, sex, and ethnicity. In addition, members will rotate off of the committee at intervals, thereby allowing other investigators to participate as committee members and receive additional training in RCR. Committee members are encouraged to continue their own education in topics related to research ethics, either through personal reading and research or through attendance at meetings.

Initiatives taken on by the Scientific Ethics Committee are listed in Table 1. The first act of the newly formed

TABLE 1. Activities of the BHTRI Scientific Ethics Committee

Posters advertising committee membership and availability
Intranet site with links to resources for education and training
Introductory RCR training to incoming research personnel
Quarterly ethics seminars for all personnel -Past topics:
Authorship and publication
Conduct and misconduct in scientific research
Conflict of interest
Acquisition and distribution of book *On Being A Scientist: A Guide to Responsible Conduct of Research* to research staff

committee was to place posters within the BHTRI, so that research staff could identify the committee members. Furthermore, a site was established on the BHTRI intranet with links to resources for education and training (e.g., ORI education sites) and an e-mail address was established to field questions from individuals who prefer this method of communication. The committee provides RCR training to the BHTRI investigators on a quarterly basis in the form of a research ethics seminar series; previous topics have included authorship and publication, conduct and misconduct in scientific research, and conflict of interest. Although our emphasis to date has been on issues specific to RCR, this forum is also appropriate to investigate other "hot" ethical issues in biomedicine, to potentially include topics such as use of animals and humans in research, end-of-life issues, and stem cell research. With command support, we have been able to bring in extramural experts as seminar speakers. We have also established a relationship with the Center for Medical Humanities and Ethics at the University of Texas Health Science Center at San Antonio and have used some of their noted speakers.

All investigators within the BHTRI receive a copy of *On Being A Scientist: A Guide to Responsible Conduct of Research*,[1] the book from which the quote opening this article is taken. All investigators are encouraged to read the book because it provides a short primer to RCR issues with case studies. In addition to the book, investigators new to the BHTRI are provided with a brief face-to-face discussion of basic concepts in research ethics and are made aware of the existence of the Scientific Ethics Committee and the availability of its members to provide help and guidance if needed. Such an oral primer on research ethics has also been provided to physicians coming into surgical fellowships within the institute.

In sum, the intent of the committee is to foster an institute-wide culture in which ethical issues are discussed openly and freely and in which investigators are given essential training and guidance in the best practices in research ethics. Importantly, the success of a committee such as this requires command support, a condition that has been met at BHTRI. It should also be noted that research ethics is constantly evolving, and any ethics committee must continue its own education and evolve accordingly. From a DoD perspective, it will be of interest to see whether such evolution results in the adoption of elements of the academic model, such as requirements for Research Integrity Officers and RCR training. In our view, it is essential that DoD laboratories and/or the DoD command structure learn from the civilian community as well as take advantage of their recent advances in promulgating research ethics. Although not directed by DoD regulation, research elements of the BHTRI (the US Army Institute of Surgical Research and the Naval Medical Research Unit) have already adopted some of these civilian policies by appointing Research Integrity Officers, whose job is to implement a command policy that delineates specific procedures for investigation of allegations of scientific misconduct. In addition, these individuals act as liaisons to the Scientific Ethics Committee (but will not serve on the committee) to suggest future RCR training topics specific to issues of scientific misconduct that may have arisen.

Will the establishment of a local Scientific Ethics Committee or a national ORI abolish all scientific misconduct? Of course not. This is so because science is performed by humans with differing motivations and value systems. However, it is essential that we provide information to those not formally trained in the research process and that we provide continued education to those who have been formally trained. We end therefore with a quote from Albert Einstein: "Some people say that it is the intellect which makes a great scientist. They are wrong: it is character."

AUTHORSHIP

K.L.R. and J.F.K. produced the first draft of the article, based on activities of the Scientific Ethics Committee, of which all coauthors (except L.H.B.) are members and contributors. L.H.B. originally established the Scientific Ethics Committee and provided input into its mission and activities. All coauthors edited the article and approved the final version.

DISCLOSURE

Funding was provided by the US Army Medical and Materiel Command, Combat Casualty Care Research Program. K.L.G. is a military service member (or employee of the US Government). This work was prepared as part of her official duties. Title 17 United States Code Section 105 provides that ''Copyright protection under this title is not available for any work of the United States Government.'' Title 17 United States Code Section 101 defines a US Government work as a work prepared by a military service member or employee of the US Government as part of that person's official duties. The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Departments of the Army, Air Force or Navy, or the Department of Defense.

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