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CITI Collaborative Institutional Training Initiative

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Introduction to the Responsible Conduct of Research

From: Introduction to the Responsible Conduct of Research.

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THERE IS NO ONE BEST WAY TO UNDERTAKE research, no universal method that applies to all scientific investigations. Accepted practices for the responsible conduct of research can and do vary from discipline to discipline and even from laboratory to laboratory. There are, however, some important shared values for the responsible conduct of research that bind all researchers together, such as:

- ▶ Honesty - conveying information truthfully and honoring commitments.
- ▶ Accuracy- reporting findings precisely and taking care to avoid errors.
- ▶ Efficiency -using resources wisely and avoiding waste.
- ▶ Objectivity - letting the facts speak for themselves and avoiding improper bias.

At the very least, responsible research is research that is built on a commitment to these and other important values that define what is

meant by integrity in research. Rules of the Road, presents a brief overview of the different ways research responsibilities are defined, ranging from formal regulations to informal codes and common practices.

The Rules of the Road

How should you conduct your research? What practices should you follow? The public and their professional colleagues expect researchers to follow many rules and commonly accepted practices as they go about their work advancing knowledge and putting knowledge to work. Responsible conduct in research is conduct that meets this expectation. Society's expectations for the responsible conduct of research are complex and not always well defined. Becoming a responsible researcher is not like becoming a responsible driver. Responsible driving is clearly defined through laws and written down in drivers' manuals. Before individuals are allowed to drive, they are tested on both their knowledge of the rules of the road and their skills. Then, licensed drivers are constantly reminded of their responsibilities by signs, traffic signals, and road markings. They also know that their behavior as drivers is monitored and that there are specific penalties for improper behavior.

Guidance for the responsible conduct of research is not this well organized. Some responsible practices are defined through law and institutional policies that *must be followed*. Others are set out in non-binding codes and guidelines that *should be followed*. Still other responsible practices are commonly accepted by most researchers but not written down. Instead, they are transmitted informally through mentoring, based on the understandings and values of each mentor. This situation is further complicated by the fact that researchers are not routinely tested on their knowledge of responsible practices or licensed. Moreover, their behavior as researchers is inconsistently monitored and the penalties for irresponsible behavior vary considerably. Researchers do, of course, care deeply about responsible behavior in research and pay a great deal of attention to best research practices. The fact remains, however, that it can take some effort to find out what these practices are and how to act when the complex rules for responsible practice seem to conflict with one another.

This introductory module describes the four basic sources of rules of the road for the responsible conduct of research:

- ▶ **Professional codes.**
- ▶ **Government regulations.**
- ▶ **Institutional policies.**
- ▶ **Personal convictions.**

Case Study

Katherine, a postdoc in Dr. Susan B.'s laboratory, has just had a manuscript accepted for publication in a prestigious research journal, conditional on a few important changes. Most importantly, the editor has requested that she significantly shorten the methods

section to save space. If she makes the requested changes, other researchers may not be able to replicate her work. Asked about the situation, Dr. B. recommends that Katherine go ahead with the changes. After all, if other researchers want more information they can always get in touch. She remains concerned that an inadequate explanation of her methods could lead other researchers to waste time and valuable research dollars attempting to replicate her work.

1. Should Katherine make the requested changes?
2. Should she be concerned about providing inadequate information to colleagues?
3. Is reducing detail in methods sections a reasonable way to go about saving valuable space in journals?
4. How can Katherine get definitive answers to these and other questions about the responsible conduct of research?

Professional self-regulation

Prior to World War II, society provided little public support for research and did not expect much from researchers in return. Researchers were more or less left alone to run their own affairs, except when they assumed other roles, as teachers, physicians, or engineers.

As professionals, researchers have not been particularly concerned about rules for self-regulation. Since the goal of research is to advance knowledge through critical inquiry and scientific experimentation, it has commonly been assumed that the normal checking that goes on in testing new ideas is sufficient to keep researchers honest. Based on this assumption, research arguably does not need specific rules for self-regulation because it is, by definition, an activity that routinely monitors itself. The lack of a perceived need for specific rules poses problems for researchers who want guidance on responsible research practices. Intellectually and professionally researchers organize their lives around fields of study. They are biologists, chemists, and physicists, increasingly working in specialized areas, such as biophysics, biochemistry, molecular biology, and so on. However, the societies that represent fields of study for the most part have not developed comprehensive guidelines for responsible research practices. Many do have codes of ethics, but most codes of ethics are simply general statements about ideals and do not contain the specific guidance researchers need to work responsibly in complex research settings.

Fortunately, there are a few important exceptions to this last generalization. Comprehensive descriptions of responsible research practices can be found in (see the resources listed at the end of this chapter for references):

- ▶ Reports and policy statements issued by the National Academy of Sciences, the American Association for the Advancement of Science, the Association of American Medical Colleges, and Sigma Xi;

- ▶ Guidance on responsible publication practices published in journals; and
- ▶ A few comprehensive professional codes.

When applicable, the guidance provided by professional societies is a good place to begin learning about responsible research practices.

National Academy of Sciences, On Being a Scientist (1995)

The scientific research enterprise, like other human activities, is built on a foundation of trust. Scientists trust that the results reported by others are valid. Society trusts that the results of research reflect an honest attempt by scientists to describe the world accurately and without bias. The level of trust that has characterized science and its relationship with society has contributed to a period of unparalleled scientific productivity. But this trust will endure only if the scientific community devotes itself to exemplifying and transmitting the values associated with ethical scientific conduct.

American Chemical Society. *The Chemist's Code of Conduct (1994)*

Chemists Acknowledge Responsibilities To:

- ▶ **The Public.** Chemists have a professional responsibility to serve the public interest and welfare and to further knowledge of science.
- ▶ **The Science of Chemistry.** Chemists should seek to advance chemical science, understand the limitations of their knowledge, and respect the truth....
- ▶ **The Profession.** Chemists should remain current with developments in their field, share ideas and information, keep accurate and complete laboratory records, maintain integrity in all conduct and publications, and give due credit to the contributions of others. Conflicts of interest and scientific misconduct, such as fabrication, falsification, and plagiarism, are incompatible with this Code.
- ▶ **The Employer.** Chemists should promote and protect the legitimate interests of their employers, perform work honestly and competently, fulfill obligations, and safeguard proprietary information.
- ▶ **Employees.** Chemists, as employers, should treat subordinates with respect for their professionalism and concern for their well-being....
- ▶ **Students.** Chemists should regard the tutelage of students as a trust conferred by society for the promotion of the student's learning and professional development
- ▶ **Associates.** Chemists should treat associates with respect, regardless of the level of their formal education, encourage them, learn with them, share ideas honestly, and give credit for their contributions. <http://www.iit.edu/departments/csep/PublicWWW/codes/coe/acs-chma.htm>

Government regulations

Public support for research grew after World War II, the public, through its elected officials, became more interested in the way research is practiced. Over time, concerns

began to surface about some of these practices, focusing initially on the use of animals and humans in research and later on research misconduct. When it appeared that the research community was not doing enough to address these concerns, government turned to regulation. Government regulations usually begin in Congress. When a potential problem is identified, Congress calls hearings to learn more about the problem and then passes legislation to fix it. The regulations covering the use of humans and animals in research as well as research misconduct stem from three acts passed by Congress:

- ▶ **The 1966 Animal Welfare Act (PL 89-544),**
- ▶ **The 1974 National Research Act (PL 93-348), and**
- ▶ **The 1985 Health Research Extension Act (PL 99-158).**

These and other research-related acts give the Federal Government the authority to regulate the research it funds. Along with the authority to address problems, Congress usually provides guidance on general objectives, but it seldom drafts detailed regulations. This job falls to the Federal agencies in the Executive Branch of government, which are responsible for carrying out the law. Federal agencies translate Congressional directives into regulations (also called rules), policies, and guidelines. In 1989, the Department of Health and Human Services (HHS) established the Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR), in response to the 1985 Health Research Extension Act. The Office of Research Integrity (ORI) was established in 1992 and assumed the responsibilities previously assigned to OSI and OSIR. In addition to responding to misconduct, ORI undertook a number of steps to promote integrity and responsible research practices.

When Federal agencies translate Congressional directives into regulations, they must follow provisions set out in the Federal Administrative Procedure Act (5 USC 551-702). As its name implies, this act establishes procedures for developing new regulations, including steps for getting public input. Before establishing a new regulation, an agency must issue a draft regulation, obtain and consider public comment, and then issue the final regulation. Each step must be published in the *Federal Register* the "official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents" (<http://www.gpoaccess.gov/fr/index.html>). Objections raised during the public comment period must be addressed before the final regulation is adopted. After it is adopted, the final regulation is incorporated into the Code of Federal Regulations and becomes official government regulatory policy that must be followed.

Agency policies and guidelines.

Executive Branch agencies have the authority to issue some policies as part of their normal operation. The National Institutes of Health (NIH), for example, has the authority to establish policies for grant awards. From time to time, it changes these policies to assure that its research funds are spent wisely and responsibly. It is in this capacity that NIH issued a special RCR "Training Grant Requirement" in 1989 and the more recent "Required Education in the Protection of Human Research Participants".

Federal agencies also issue Guidelines, which recommend but do not require a particular course of action. To help research institutions handle allegations of research misconduct ORI issued as guidelines a Model Policy and Procedures for Responding to Allegations of Scientific Misconduct (<http://ori.hhs.gov/html/policies/model.asp>). In this case, the model policy is intended to provide guidance and does not impose binding requirements on institutions. The plethora of Federal regulations, policies, and guidelines that affect research can be confusing. They do not always speak with one voice. The same aspect of a research project can be subject to regulations by more than one Federal agency, as for example the use of human or animal subjects. Common Federal regulations, such as the Federal Policy on Research Misconduct and the "Common Rule" for human subjects research, are not truly common regulations until they have been adopted by all agencies. In addition, distinctions between regulations, policies, requirements, guidelines, and recommended practices can be difficult to understand.

Required Education in the Protection of Human Research Participants

June 5, 2000 (Revised August 25, 2000) National Institutes of Health Policy: Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Background: To bolster the Federal commitment to the protection of human research participants, several new initiatives to strengthen government oversight of medical research were announced by HHS Secretary Shalala on May 30, 2000. This announcement also reminds institutions of their responsibility to oversee their clinical investigators and institutional review boards (IRBs). One of the new initiatives addresses education and training. This NIH announcement is developed in response to the Secretary's directive. <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

Researchers are well advised to seek help when it comes to understanding Federal and state research regulations. The Federal agencies that regulate research have comprehensive Web pages that list and explain their policies and regulations and readily answer questions. For local advice, your institutional research administrators may be the best place to begin.

Institutional policies

Research institutions (universities, hospitals, private research companies, and so on) are required by law to have policies that cover various aspects of their research programs if they accept Federal funds. They must have committees to review human and animal research. They must have procedures for investigating and reporting

research misconduct and conflicts of interest. They must approve and manage all research budgets, ensure that laboratory safety rules are followed, and follow established practices for the responsible use of hazardous substances in research. They must also provide training for researchers who use animal or human subjects in their research and for individuals supported on NIH training grants. To help manage their responsibilities, most research institutions have research offices/officers and institutional research policies. Both provide excellent sources of guidance for responsible conduct in research, since both are the products of the institution's efforts to clarify its own responsibilities. In addition, institutional policies are often more comprehensive than Federal and state policies since they must encompass the full panoply of institutional responsibilities. So, for example, many research institutions have more comprehensive definitions of research misconduct than the Federal Government to cover other practices that can undermine the integrity of research, such as the deliberate violation of research regulations, abuses of confidentiality, and even the failure to report misconduct. Most also require institutional review for more human subjects research than is required by Federal regulation. Large research institutions usually have Web sites that contain some or all of the following information:

- ▶ **Copies of institutional research policies,**
- ▶ **Links to state and Federal policies,**
- ▶ **Required forms and instructions for completing them,**
- ▶ **Responsible conduct of research training programs, and**
- ▶ **Lists of key personnel.**

There is, of course, little or no coordination across different research institutions, so the information on an institution's Web site pertains only to that institution. But if you are looking for a comprehensive set of rules of the road for responsible research, check your home institution's research administration Web site or one from a comparable institution.

For Example:

Stanford University - Research Policy Handbook
Document 2.1

Title: Principles Concerning Research Originally
issued: Dec 8, 1971

Current version: Dec 8, 1971

Classification: Stanford University Policy

Summary: Presents broad principles to guide the
research enterprise and assure the integrity of
scholarly inquiry at Stanford University.

<http://www.stanford.edu/dept/DoR/rph/2-1.html>

1d. Personal responsibility

As important as rules of the road are for the responsible conduct of research, they have two important limitations. First, rules generally set minimum standards for behavior rather than strive for the ideal. The rules say that you can drive at 65 miles per hour over a stretch of road, but there may be times or circumstances when 55 would be

better. If you use human subjects in research, you must follow specific rules, but there may be situations in which you should strive for a higher standard of conduct. Responsible research requires more than simply following rules. Second, rules will not resolve some of the personal conflicts and moral dilemmas that arise in research. Journals have rules against listing undeserving authors on papers (individuals who have not made significant contributions to the research described in the paper). These same rules do not tell you what to do if the undeserving author can have a significant influence on your career. Rules also cannot replace the critical reasoning skills needed to assess ethically controversial human or animal experiments or conflicts of interest. Researchers will face ethical dilemmas in research. They should be able to recognize these dilemmas and know how to resolve them. The rules of the road for research therefore need to be supplemented with good judgment and a strong sense of personal integrity. When meeting deadlines, you can cut corners by filling in a few missing data points without actually running the experiments or adding a few references to your notes that you have not read. You can resist sharing data with colleagues or leave some information on method out of a publication to slow down the competition. You can ignore your responsibilities to students or a mentor in order to get your own work done. You can do all of these things and more, but should you?

In the final analysis, whatever decision you make when you confront a difficult decision about responsibility in research, you are the one who has to live with the consequences of that decision. If you are uncertain whether a particular course of action is responsible, subject it to one simple test. Imagine what you are preparing to do will be reported the next day on the front page of your local newspaper. If you are comfortable having colleagues, friends, and family know what you did, chances are you acted responsibly, provided, of course, you also understand your responsibilities as a researcher.

Questions for discussion

- ▶ Is research a profession?
- ▶ How do researchers learn about the responsible conduct of research?
- ▶ How should researchers learn about the responsible conduct of research?
- ▶ What factors influence researchers' attitudes toward the responsible conduct of research?
- ▶ How is integrity in research monitored?

- ▶ Is self-regulation of integrity in research effective?

Resources

Policies, Reports, and Policy Statements

- ▶ Sigma Xi. *Honor in Science*, New Haven, CN: Sigma Xi, 1984. (available at: <http://www.sigmaxi.org/publications/>)
- ▶ National Academy of Sciences. Committee on the Conduct of Science. *On Being a Scientist: Responsible Conduct in Research*, 2nd ed. Washington, DC: National Academy Press, 1995. (available at: <http://www.nap.edu>)

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- ▶ Association of American Medical Colleges. *Developing a Code of Ethics in Research: A Guide for Scientific Societies*, Washington, DC: AAMC, 1997. (available at: <http://www.aamc.org/publications/ersn.htm>)
- ▶ National Institutes of Health. *Guidelines for the Conduct of Research in the Intramural Research Programs at NIH*, 1997. (available at: <http://www.nih.gov/campus/irnews/guidelines.htm>)
- ▶ Institute of Medicine. *The Responsible Conduct of Research in the Health Sciences*, Washington, DC: National Academies of Science, 1989. (available at: <http://www.nap.edu/books/0309062373/html/>)

General Information Web Sites

- ▶ American Association for the Advancement of Science. *Integrity in Scientific Research*, 2000. <http://www.aaas.org/spp/video/>. (Information on five videos on integrity in research.)
- ▶ Bird, S, Spier, R, eds. *Science and Engineering Ethics*, 1995 ff. <http://www.opragen.co.uk/>. (Includes articles on the responsible conduct of research.)
- ▶ National Institutes of Health. *Research Conduct and Ethics Instruction Materials*, nd. <http://www1.od.nih.gov/oir/sourcebook/ResEthicsCases/cases-toc.htm>
- ▶ North Carolina State University. *Research Ethics Initiative*, 2003. <http://www.fis.ncsu.edu/Grad/ethics/>
- ▶ Office of Research Integrity. *Home Page*, 2003. <http://ori.hhs.gov/>
- ▶ Online Ethics Center for Engineering and Science. *Home Page*, 2003. <http://onlineethics.org/RCR> Education Consortium. *Home Page*, 2002-2004. <http://rcrec.org/>
- ▶ Shamoo, AE, ed. *Accountability in Research: Policies and Quality Assurance*, 1994 ff. <http://www.tandf.co.uk/journals/titles/08989621.html>. (Includes articles on research integrity and related issues.)

Additional Reading

- ▶ Barnbaum, DR, Byron, M. *Research Ethics: Text and Readings*, Upper Saddle River, NJ: Prentice Hall, 2001.
- ▶ Beach, D. *The Responsible Conduct of Research*, New York: VCH Publishers, 1996.
- ▶ Bulger, RE, Heitman, E, Reiser, SJ. *The Ethical Dimensions of the Biological and Health Sciences*, 2nd ed. Cambridge, UK; New York: Cambridge University Press, 2002.
- ▶ Elliott, D, Stern, JE. *Research Ethics: A Reader*, Hanover, NH: Published by

University Press of New England for the Institute for the Study of Applied and Professional Ethics at Dartmouth College, 1997.

- ▶ Frankel, M, Bird, S. eds. "The Role of Scientific Societies in Promoting Research Integrity," *Science and Engineering Ethics* 9, 2 (2003).
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- ▶ Korenman, SG, Shipp, AC. *Teaching the Responsible Conduct of Research through a Case Study Approach: A Handbook for Instructors*, Washington, DC: Association of American Medical Colleges, 1994.
- ▶ Macrina, FL. *Scientific Integrity: An Introductory Text with Cases*, 2nd ed. Washington, DC: ASM Press, 2000.
- ▶ Penslar, RL. *Research Ethics: Cases and Materials*, Bloomington: Indiana University Press, 1995.
- ▶ Resnik, DB. *The Ethics of Science : An Introduction, Philosophical Issues in Science*, London; New York: Routledge, 1998.
- ▶ Shamo, AE, Resnik, DB. *Responsible Conduct of Research*, New York: Oxford University Press, 2003.
- ▶ Sigma Xi. *The Responsible Researcher: Paths and Pitfalls*, 1999.
- ▶ Stern, JE, Elliott, D. *The Ethics of Scientific Research: A Guidebook for Course Development*, Hanover, NH: University Press of New England, 1997.
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