

The Six Domains of Research Ethics

A Heuristic Framework for the Responsible Conduct of Research¹

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The United States Public Health Service (PHS) recently issued its “PHS Policy on Instruction in the Responsible Conduct of Research (RCR),”³ which requires that “research staff [who work on PHS-supported research projects] . . . shall complete a basic program of instruction in the responsible conduct of research.” The policy includes a list of nine “Core Instructional Areas” that must be covered. In a sense, the core instructional areas represent the Federal view of the scope of the responsible conduct of research. The areas are:

1. Data acquisition, management, sharing, and ownership
2. Mentor/trainee responsibilities
3. Publication practices and responsible authorship
4. Peer review
5. Collaborative science
6. Human subjects
7. Research involving animals
8. Research misconduct
9. Conflict of interest and commitment

The purpose of this essay is not to offer a critique of the policy, nor of the core instructional areas. I have no quibbles with what PHS considers core; but I would like to offer what I consider a useful and complementary conceptual framework for the scope of research ethics. (A number of informal and formal commonly-used terms in this area, such as “research integrity,”

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³ The policy can be found at <http://ori.dhhs.gov/html/programs/rcrcontents.asp>. See also Pimple 2000b.

“misconduct,” and “questionable research practices,” are described in Appendix A and the details of the PHS Core Instructional Areas can be found in Appendix B.)

The presentation of my heuristic takes two steps, first offering a very compact framework, then unpacking it.

Truth, fairness, and wisdom⁴

Concerns about the ethics of any particular research product or project can be divided into three categories: (A) Is it true? (B) Is it fair? (C) Is it wise?

The first question, “Is it true?”, concerns the relationship of the research results to the physical world. Do the data and conclusions really correspond to reality? If data are made up (fabricated) or fixed up (falsified), they are not true. To a degree, this question could be re-stated as, “Is it good science?”

The second question, “Is it fair?”, concerns social relationships within the world of research. In this category belong issues such as relationships among researchers (authorship and plagiarism); between researchers and human subjects (informed consent); between researchers and animal subjects (animal welfare); and relationships between researchers, their sponsoring institutions, funding agencies, and the government. For example, although true reports can be published without citing previous publications, or without securing informed consent from human subjects, these are not fair research practices.

The third question, “Is it wise?”, concerns the relationship between the research agenda and the broader social and physical world, present and future. Will the research improve the human condition, or damage it? Will it lead to a better world, or a worse one? Or less grandly, which of

⁴ The remainder of this paper is adapted from Pimple 1998a and Pimple 2000c.

the many possible lines of research would we be better off pursuing? We have finite time and money for pursuing research, and the wisdom of research programs is a valid question in research ethics. These are the kinds of questions people have in mind when they debate the ethics of human cloning.

These three questions provide a handy pocket-size guide to the responsible conduct of research, capturing the heart of the issue in a concise formulation.

The questions are meant to be organized from the smallest to the largest – from the (relatively) simple question of whether a research report is true to the much more complicated question of which research projects are morally acceptable and which are morally prohibited.

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I have found that the most logical and intuitive way of elaborating on these three questions is to expand them into six domains, as follows. The lists are intended to be sorted in a rough way from the basic to the complex; numbers are provided for ease of reference and are not intended to convey a sense of precision about the arrangement of items.

Is it true?

1. Scientific integrity – The relationship between research and the truth.
 - 1.1. basic competence
 - 1.2. data manipulation
 - 1.3. statistical methods
 - 1.4. falsification
 - 1.5. fabrication

Is it fair?

2. Collegiality – Relationships among researchers.
 - 2.1. authorship
 - 2.2. data sharing and timely publishing
 - 2.3. plagiarism

- 2.4. peer review
- 2.5. confidentiality
- 2.6. candor
- 2.7. mentorship
3. Protection of human subjects – Relationships between researchers and human subjects.
 - 3.1. the Belmont Report (1979) – protection from harms: respect for persons (autonomy); beneficence (plus non-maleficence); justice
 - 3.2. post-Belmont – access to treatments
 - 3.3. informed consent
 - 3.4. assent
 - 3.5. confidentiality and anonymity
 - 3.6. deceit
 - 3.7. debriefing
 - 3.8. research risks and benefits
4. Animal welfare – Relationships between researchers and animal subjects.
 - 4.1. the 3 R's (replacement, reduction, refinement)
 - 4.2. pain and suffering
 - 4.3. enrichment
 - 4.4. animal “rights”
5. Institutional integrity – Relationships between researchers, their sponsoring institutions, funding agencies, and the government.
 - 5.1. conflict of interest
 - 5.2. conflict of commitment
 - 5.3. regulatory compliance
 - 5.4. data retention
 - 5.5. institutional oversight
 - 5.6. institutional demands and support

Is it wise?

6. Social responsibility – The relationship between research and the common good.
 - 6.1. research priorities
 - 6.2. fiscal responsibility
 - 6.3. public service
 - 6.4. public education
 - 6.5. advocacy by researchers
 - 6.6. environmental impact
 - 6.7. forbidden knowledge

The six domains are not hermetically sealed. Many items could be placed into more than one category. Taking perhaps the most obvious example, most of the items under the 3 (the

protection of human subjects) and 4 (animal welfare) also fall under 5.3, “regulatory compliance.” But a concern with protecting human subjects or with animal welfare is not precisely synonymous with a concern for regulatory compliance. Following the rules is not exactly the same as being ethical; the two often overlap, and are generally intended to overlap. Sometimes, however, following rules serves no moral value other than the value of following rules. Furthermore, sometimes morality demands more than rules do, and sometimes morality actually demands actions that run counter to the rules.

I think both the three-question and the six-domain versions of this heuristic are useful, in part because they have some intuitive value. For me, and I assume for others, contemplating “relationships among researchers” leads almost immediately into insights about ethical issues, how they arise, and how they can be justly resolved.

Some of the similarities and differences between the Six Domains and the PHS Core Instructional Areas, detailed in Appendix C, are instructive. I will mention only three here:

(a) The first Core Instructional Area, “data acquisition, management, sharing, and ownership,” ranges over four of the six Domains, leaving out only domains 4 (Animal Welfare) and 6 (Social Responsibility). This discrepancy highlights the complexity of the issues.

(b) In most cases, the PHS Core Instructional Areas are more thoroughly spelled out than the Six Domains; a glaring exception is “Research Involving Animals,” which covers all four of the Six Domains sub-categories with the simple phrase, “treatment of animals.” Perhaps this indicates inadequate attention to the topic.

(c) None of the PHS Core Instructional Areas clearly correspond to any of the items in Domain 6 (Social Responsibility), a disturbing gap.

I rather doubt that I have overlooked a seventh domain; if I have, I would be delighted to be corrected. On the other hand, I have no doubt that more sub-categories could be added and the existing items refined. I certainly could explain what I mean by each sub-category in much more detail. I will not, however, do so here, in part because it would be an involved and lengthy process, but more because the value of this heuristic is not in providing an exhaustive list – an encyclopedia of ethical issues in research – but in providing a framework for thinking about the responsible conduct of research. Generating the details and correcting this list is therefore left as an exercise for the reader.

Appendix A: Commonly-used terms

A number of clearly related terms are commonly used by people concerned with the responsible conduct of research. There is some overlap, but the terms are conceptually distinct, each mapping out a particular territory and useful in particular ways.

- Misconduct in science or research misconduct. “Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results” (Office of Science and Technology Policy 2000: 76262). Behaviors that justify Federal intervention.⁵

⁵ This Federal definition of research misconduct was proposed in October of 1999 and adopted December 6, 2000. It was intended to replace the two existing definitions (see below) with one single definition and policy.

The two earlier definitions essentially boil down to “fabrication, falsification, plagiarism, or other seriously deviations from accepted practices.” The new definition excludes the controversial “other serious deviations” clause. The complete definitions are as follows:

The Public Health Service (PHS) definition:

“Misconduct” or “Misconduct in Science” means 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. [PHS 1989:32449]

The National Science Foundation (NSF) definition:

“Misconduct” means (1) fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from activities funded by NSF; or (2) retaliation of any

- Questionable research practices. Proposed by the Committee on Science, Engineering, and Public Policy (COSEPUP) of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine in 1992 to elucidate and eliminate the “other serious deviations” clause in the definition of misconduct. “Questionable research practices are actions that violate traditional values of the research enterprise and that may be detrimental to the research process,” but may not be as serious as misconduct (COSEPUP 1992:28). Examples include
 - Failing to retain significant research data for a reasonable period.
 - Maintaining inadequate research records, especially for results that are published or are relied on by others;
 - Conferring or requesting authorship on the basis of a specialized service or contribution that is not significantly related to the research reported in the paper;
 - Refusing to give peers reasonable access to unique research materials or data that support published papers;
 - Using inappropriate statistical or other methods of measurement to enhance the significance of research findings;
 - Inadequately supervising research subordinates or exploiting them; and
 - Misrepresenting speculations as fact or releasing preliminary research results, especially in the public media, without providing sufficient data to allow peers to judge the validity of the results or to reproduce the experiments. [COSEPUP 1992:28, emphasis in original]
- Pathological science. “Cases where there is no dishonesty involved but where people are tricked into false results by a lack of understanding about what human beings can do to themselves in the way of being led astray by subjective effects, wishful thinking or threshold interactions” (Irving Langmuir, quoted in Carroll 2000).
- Research integrity. A concern with whether publicly presented research accurately reflects the scientific findings – in other words, research tainted by fabrication or falsification.
- Regulatory compliance. A concern with following the rules (regulations and laws), including the rules of a lab, research group, department, university, state, or country.

“Research integrity” and “regulatory compliance” are fairly narrow concerns. The broadest, most inclusive terms are

- Research ethics
- The responsible conduct of research (RCR)

kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith. [NSF 1991:22287]

See Pimple 1997 for a discussion of these definitions and Pimple 2000a for a comment on the new definition.

I have not yet been able to discern a meaningful difference between the last two terms, but RCR is clearly becoming the term of favor. Perhaps RCR is preferred by some because using the word “ethics” seems too preachy or moralistic or abstract.

Appendix B: Details of the PHS Core Instructional Areas

1. Data acquisition, management, sharing, and ownership – Accepted practices for acquiring and maintaining research data. Proper methods for record keeping and electronic data collection and storage in scientific research. Includes defining what constitutes data; keeping data notebooks or electronic files; data privacy and confidentiality; data selection, retention, sharing, ownership, and analysis; data as legal documents and intellectual property, including copyright laws.

2. Mentor/trainee relationships – The responsibilities of mentors and trainees in predoctoral and postdoctoral research programs. Includes the role of a mentor, responsibilities of a mentor, conflicts between mentor and trainee, collaboration and competition, selection of a mentor, and abusing the mentor/trainee relationship.

3. Publication practices and responsible authorship – The purpose and importance of scientific publication, and the responsibilities of the authors. Includes topics such as collaborative work and assigning appropriate credit, acknowledgements, appropriate citations, repetitive publications, fragmentary publication, sufficient description of methods, corrections and retractions, conventions for deciding upon authors, author responsibilities, and the pressure to publish.

4. Peer review – The purpose of peer review in determining merit for research funding and publications. Includes topics such as, the definition of peer review, impartiality, how peer review works, editorial boards and ad hoc reviewers, responsibilities of the reviewers, privileged information and confidentiality.

5. Collaborative science – Research collaborations and issues that may arise from such collaborations. Includes topics such as setting ground rules early in the collaboration, avoiding authorship disputes, and the sharing of materials and information with internal and external collaborating scientists.

6. Human subjects – Issues important in conducting research involving human subjects. Includes topics such as the definition of human subjects research, ethical principles for conducting human subjects research, informed consent, confidentiality and privacy of data and patient records, risks and benefits, preparation of a research protocol, institutional review boards, adherence to study protocol, proper conduct of the study, and special protections for targeted populations, e.g., children, minorities, and the elderly.

7. Research Involving Animals – Issues important to conducting research involving animals. Includes topics such as definition of research involving animals, ethical principles for conducting

research on animals, Federal regulations governing animal research, institutional animal care and use committees, and treatment of animals.

8. Research misconduct – The meaning of research misconduct and the regulations, policies, and guidelines that govern research misconduct in PHS-funded institutions. Includes topics such as fabrication, falsification, and plagiarism; error vs. intentional misconduct; institutional misconduct policies; identifying misconduct; procedures for reporting misconduct; protection of whistleblowers; and outcomes of investigations, including institutional and federal actions.

9. Conflict of Interest and Commitment – The definition of conflicts of interest and how to handle conflicts of interest. Types of conflicts encountered by researchers and institutions. Includes topics such as conflicts associated with collaborators, publication, financial conflicts, obligations to other constituencies, and other types of conflicts.

Appendix C: Comparison of the PHS Core Instructional Areas with the Six Domains

The PHS Core Instructional Areas and the Six Domains are not intended to serve quite the same purpose and so cannot be compared precisely. The PHS list is intended to be a curricular guideline, and as such it rightly includes items that should be taught in an RCR course (for example, “the definition of human subjects research, ethical principles for conducting human subjects research”), but which are simply background for the Six Domains. In the list below, I have excised the items in the PHS list that cannot really be directly compared to the items in the Six Domains list, as well as the sentences that essentially repeat or elaborate on the heading. I have indicated by number where the other items fit in the Six Domains.

1. Data acquisition, management, sharing, and ownership – . . . Includes . . . keeping data notebooks or electronic files [1.1]; data privacy and confidentiality [3.5]; data selection [1.1, 1.2, 1.3], retention [5.4], sharing [2.2], ownership [2.1, 2.2, 2.3, 5.3, 5.4, 5.5, 5.6], and analysis [1.1, 1.2, 1.3, 2.6]; data as legal documents and intellectual property, including copyright laws [2.1, 2.2, 2.3, 5.3, 5.4, 5.5, 5.6].

Comment: A hodgepodge of Six Domains items, drawing from Domains 1, 2, 3, and 5, leaving out only 4 (Animal Welfare) and 6 (Social Responsibility). The long lists after “data ownership” and “copyright laws” may show a gap in the Six Domains (should there be one or two items, rather than seven, that correspond to these concepts?), or they may show that the concepts of data ownership and copyright laws tremendously complex, perhaps more complex than implied by their short names.

2. Mentor/trainee relationships – . . . Includes the role of a mentor, responsibilities of a mentor, conflicts between mentor and trainee, collaboration and competition, selection of a mentor, and abusing the mentor/trainee relationship [2.7].

Comment: Expands on 2.7.

3. Publication practices and responsible authorship – . . . Includes topics such as collaborative work and assigning appropriate credit [2.1], acknowledgements [2.1], appropriate citations [2.1], repetitive publications [2.2], fragmentary publication [2.2], sufficient description of methods [2.6], corrections and retractions [2.6], conventions for deciding upon authors [2.1], author responsibilities [2.1], and the pressure to publish [5.6].

Comment: Expands on 2.1 (authorship), 2.2 (data sharing and timely publication), and 2.6 (candor). In the Six Domains scheme, “the pressure to publish” does not fall in the same category as these others; I locate it in 5.6 (institutional demands and support).

4. Peer review – . . . Includes topics such as . . . impartiality, how peer review works, editorial boards and ad hoc reviewers, responsibilities of the reviewers, privileged information and confidentiality [2.4].

Comment: Expands on 2.4.

5. Collaborative science – . . . Includes topics such as setting ground rules early in the collaboration [2.1, 2.2], avoiding authorship disputes [2.2], and the sharing of materials and information with internal and external collaborating scientists [2.2].

Comment: Expands on 2.1 (authorship) and 2.2 (data sharing and timely publishing). An argument could be made for including some or all of these under 5 (Institutional Integrity), especially “setting ground rules” and “avoiding authorship disputes”.

6. Human subjects – . . . Includes topics such as . . . informed consent [3.3], confidentiality and privacy of data and patient records [3.1, 3.5, 3.8], risks and benefits [3.1, 3.8], preparation of a research protocol [1.1, 5.3], institutional review boards [5.3, 5.5], adherence to study protocol [1.1, 5.3], proper conduct of the study [1.1, 5.3], and special protections for targeted populations, e.g., children, minorities, and the elderly [3.1, 3.2, 3.8, 5.3].

Comment: Mixes issues from Domain 3 (Protection of Human Subjects) and 5 (Institutional Integrity). While it is natural and desirable to cover institutional review boards when discussing the protection of human subjects, it would be regrettable (as argued above) if the protection of human subjects were to be reduced to regulatory compliance. I list some items, such as “preparation of a research protocol,” as falling under 1.1 (basic competence), an arguable categorization.

7. Research Involving Animals – . . . Includes topics such as . . . Federal regulations governing animal research [5.3], institutional animal care and use committees [5.3, 5.5], and treatment of animals [4.1, 4.2, 4.3, 4.4].

Comment: The emphasis here is on regulatory compliance and institutional oversight (5.3 and 5.5). In contrast to categories discussed above, the PHS list has much less detail on “the treatment of animals” than the Six Domains list.

8. Research misconduct – . . . Includes topics such as fabrication [1.5], falsification [1.4], and plagiarism [2.3]; error [1.1] vs. intentional misconduct [5.3, 5.5]; institutional misconduct policies [5.3]; identifying misconduct [5.5]; procedures for reporting misconduct [5.3, 5.5]; protection of whistleblowers [5.3, 5.5]; and outcomes of investigations, including institutional and federal actions [5.3, 5.5].

Comment: Falsification, fabrication, and error are quite distinct conceptually from plagiarism, a nuance lost in the PHS listing (see Pimple 2000a). Expands on 5.3 (regulatory compliance) and 5.5 (institutional oversight).

9. Conflict of Interest and Commitment – . . . Includes topics such as conflicts associated with collaborators [2.1, 2.2], publication [2.1, 2.2], financial conflicts [5.1], obligations to other constituencies [5.2], and other types of conflicts.

Comment: A split focus between Domain 2 (Collegiality) and 5 (Institutional Integrity).

Overall, I think the two categorizations complement each other. Although the PHS list tends to be more explicit in unpacking its concepts, as evidenced by the comments that the PHS list “elaborates on” one or another of the Six Domains items, it is striking that not one of the PHS issues touches on Domain 6 (Social Responsibility).

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