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Six Domains of Research Ethics
A Heuristic Framework for the Responsible Conduct of Research

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ABSTRACT: The purpose of this paper is to provide a simple yet comprehensive organizing scheme for the responsible conduct of research (RCR). The heuristic offered here should prove helpful in research ethics education, where the many and heterogeneous elements of RCR can be bewildering, as well as research into research integrity and efforts to form RCR policy and regulations. The six domains are scientific integrity, collegiality, protection of human subjects, animal welfare, institutional integrity, and social responsibility.

The study of research ethics spans innumerable and diverse fields of inquiry, ranging from particle physics to oral history, archeology to bionanotechnology, and touches on issues as localized as student-mentor relationships, and as global as biomedical research in developing countries. In some cases the stakes are high, impinging human health and environmental integrity; in other cases the stakes are, in the grand scheme, quite low and of interest primarily (if not quite only) to a few researchers involved in a dispute. As a field of study, research ethics is, not surprisingly, incoherent. This article offers a framework intended to bring some order to the field.

The United States Public Health Service (PHS) recently issued its “PHS Policy on Instruction in the Responsible Conduct of Research (RCR)” 1 which states that “research staff [who work on PHS-supported research projects] … shall complete a

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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 a 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. Rather, 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”, “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.)

**Truth, fairness, and wisdom**

For purposes of stimulating discussion and speculation, I suggest that 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 presentation here is intentionally provocative.

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.

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See also reference 2. As of this writing, the PHS policy on RCR instruction has been suspended, but the Office of Research Integrity still supports the policy and is proceeding with plans to implement and support it.\(^3\)

The following section is adapted and expanded from reference 4.
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 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 many people have in mind when they debate the ethics of human cloning.

These three questions provide a succinct 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. They are also meant to stimulate discussion, even controversy (a useful pedagogical tool). For example, although attention to truth can hardly be avoided when discussing the responsible conduct of research, the concepts of “truth” and even “reality” are more problematic today than they were in Bacon’s time. Even people unimpressed by postmodernism will recognize that the conclusions of a falsified or fabricated report could still be accurate (“true”), and that some reports that are not accurate (not true) do not imply any misdeed on the part of the researcher – as strange as the phrase may seem, there really are “honest mistakes.” This deliberately oversimplified presentation should encourage teachers and students to wrestle with the concepts of truth, accuracy, the goals of science, the source(s) of science’s authority, and other fundamental issues in the responsible conduct of research.

Six Domains

Expanding the three questions into six domains provides a logical, intuitive, and less simplified way of organizing the responsible conduct of research. The subcategories are numbered for ease of reference only; the numbers are not intended to convey a sense of precision about the arrangement of items.

Is it true?

   1.1. basic technical competence (including experimental design)
   1.2. data manipulation
   1.3. statistical methods
   1.4. falsification
   1.5. fabrication
   1.6. unintentional bias
K. D. Pimple

Is it fair?
   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
   3.1. the Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research) – 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
   4.1. 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?
   6.1. 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 3 (the protection of human subjects) and 4 (animal welfare) also fall under 5.3, “regulatory compliance”. But concerns with protecting human subjects and with animal welfare are not precisely synonymous with a concern for regulatory compliance: following the rules is not exactly the same as being ethical. Certainly the two often overlap, and are generally intended to overlap, but sometimes following rules serves no moral value other than that of following rules. Indeed, sometimes morality demands more than rules do, and sometimes morality actually demands actions that run counter to the rules.

The sub-categories are not intended to be exhaustive; I have no doubt that more could be added and the existing items refined. Furthermore, each sub-category could be explained in detail, but I do not do so here because my goal is not to provide an encyclopedia, but a framework or system – the difference is something like that between a multiplication table and an algorithm for multiplying. Generating the details and correcting the list are therefore left as an exercise for the reader.

Applying the Framework

The PHS Core Instructional Areas, being built on hard experience, make sense to anyone familiar with the public catalog of research abuses over the last quarter century, but to a novice they might look like a semi-random hodgepodge. The Six Domains heuristic framework is intended to provide an easy entree to newcomers and an organizational metaphor for experts.

The following are three examples of this framework’s utility.

Research Misconduct

Since 1989, when the Federal government reluctantly adopted policies to deal with irresponsible research practices, research misconduct has essentially been defined as fabrication, falsification, and plagiarism. (An interesting account of the history of the concept of misconduct in science can be found in reference 7; see also Appendix A.) Here are the relevant portions of the current, Federal-wide definition of misconduct, adopted in 2000:

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

The practical difference between fabrication and falsification is one of degree rather than kind. Both corrupt the research record by misrepresenting a wholly (fabrication) or partially (falsification) fictitious research report as honestly derived.
findings. There can be no question that pawning fiction off as fact is contrary to the norms – indeed, to the very definition – of science.

Plagiarism, however, is a different kind of offense. One ideal in science, identified by Robert Merton as “disinterestedness” holds that what matters is the finding, not who makes the finding. Under this norm, scientists do not judge each others’ work by reference to the race, religion, gender, prestige, or any other incidental characteristic of the researcher; the work is judged by the work, not by the worker. In this light, plagiarism seems irrelevant to science. No harm would be done to the Theory of Relativity if we discovered that Einstein had plagiarized it. (A great deal of harm would be done to Einstein’s memory, but that is sociology or history or biography, not science.)

The Six Domains framework helps clarify what is at stake with plagiarism; it is an offense against the community of scientists, rather than against science itself. Who makes a particular finding will not matter to science in one hundred years, but today it matters deeply to the community of scientists. Plagiarism is a way of stealing credit, of gaining credit where credit is not due, and credit, typically in the form of authorship, is the coin of the realm in science. An offense against scientists qua scientists is an offense against science, and in its way plagiarism is as deep an offense against scientists as falsification and fabrication are offenses against science.

Data management

The first Core Instructional Area, “data acquisition, management, sharing, and ownership,” corresponds to Domains 1, 2, 3, and 5, leaving out only 4 (Animal Welfare) and 6 (Social Responsibility). A point-by-point comparison of the details of the PHS Core Instructional Areas (see Appendix B) and the Six Domains highlights the differences in the approaches:

<table>
<thead>
<tr>
<th>PHS Core Instructional Area 1: Data acquisition, management, sharing, and ownership</th>
<th>Six Domains</th>
</tr>
</thead>
<tbody>
<tr>
<td>keeping data notebooks or electronic files</td>
<td>1.1. basic technical competence (including experimental design)</td>
</tr>
<tr>
<td>data privacy and confidentiality</td>
<td>3.5 confidentiality and anonymity</td>
</tr>
<tr>
<td>data selection</td>
<td>1.1. basic technical competence (including experimental design)</td>
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<tr>
<td></td>
<td>1.2. data manipulation</td>
</tr>
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<td></td>
<td>1.3. statistical methods</td>
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<tr>
<td>[data] retention</td>
<td>5.4. data retention</td>
</tr>
<tr>
<td>[data] sharing</td>
<td>2.2. data sharing and timely publishing</td>
</tr>
<tr>
<td>[data] ownership</td>
<td>2.1. authorship</td>
</tr>
<tr>
<td></td>
<td>2.2. data sharing and timely publishing</td>
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<td></td>
<td>2.3. plagiarism</td>
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<td></td>
<td>5.3. regulatory compliance</td>
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<td>5.4. data retention</td>
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<td></td>
<td>5.5. institutional oversight</td>
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<td></td>
<td>5.6. institutional demands and support</td>
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</tbody>
</table>
The long lists corresponding to “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 indicate that the concepts of data ownership and copyright laws are tremendously complex, perhaps more complex than implied by their short names.

Issues related to data management are clearly extremely complex and multivalent. An argument could be made that “data management” is the neglected, but essential, twin to the “scientific method.” Descriptions of the scientific method typically mention observation, hypothesis-forming, and experimentation to test the hypothesis; implied in all of this, but not stated, is that the observations, hypothesis, experimental details, and experimental results are recorded (or, in proto-science, remembered). Even more subtly, the publication of scientific findings is both dependent on adequate data management and a form of data management. Without publication (as a journal article, an oral presentation, or what have you), no activity can rightly be thought of as science. Requiring training in responsible data management is hardly less comprehensive than requiring training in the responsible conduct of research; it does not quite exist at the same level of abstraction as the other Core Instructional Areas.

Methods of recording, analyzing, and storing data fall under Domain 1 (scientific integrity), but retention of data also falls under Domain 5 (institutional integrity). Likewise, when human subjects are involved, methods of recording, reporting, and storing data also fall under Domain 4 (protection of human subjects) because of the importance of informed consent, privacy, confidentiality, anonymity, and the like. Copyright law and intellectual property both touch on collegiality (Domain 1) as well as institutional integrity (Domain 5).

The stakes involved in data management are far from intuitive or obvious, thereby making them difficult to disentangle. Use of the Six Domains framework takes a step toward simplifying a knotty challenge.
Social responsibility.
Finally, none of the PHS Core Instructional Areas clearly correspond to any of the items in Domain 6 (Social Responsibility). Although this is a disturbing gap, it is also easy to guess why issues of social responsibility are not included in the Core Instructional Areas.

First, there is no consensus on the social responsibility of science or scientists (aside from those considerations covered by the other five Domains, such as basic competence and truthfulness). Do scientists have an obligation to act as advocates? I suggest that some do, but I would not expect everyone to agree with me on this point.

Second, the Core Instructional Areas tend to focus on what an individual scientist can do. Every researcher is wholly responsible for his own acts of fabrication (if any) and for doing her part to foster collegial relationships. However, no scientist is responsible for setting the research agenda for the nation or the world.

These facts notwithstanding, I suggest that omitting social responsibility from the Core Instructional Areas is regrettable and may send an unfortunate message: Scientists have individual responsibilities, but they have no social responsibilities. Granted that no one scientist can bear the burden alone, it is still true that each scientist has an obligation to carry some part of the burden. I would not suggest in the abstract that every, or any given, scientist has a moral obligation to undertake public service (for example), but clearly science as an institution and scientists as a group do have such a moral obligation. Although in the end precisely what is demanded of any particular scientist may be difficult to identify, to me it is clear that scientists should be cognizant of this general responsibility and that training in social responsibility – even if such training were to consist of nothing more than describing and exploring science’s social responsibilities – could be beneficial.

Conclusion

Research ethics is an incoherent field (insofar as it can be considered “a field” at all). Its subject matter necessarily encompasses ageless moral truths and recent arbitrary conventions; minute details of particular actions and the broad sweep of public policy; life-and-death issues and matters just the other side of simple etiquette. The framework presented here is meant to bring some coherence to the field, to organize the components of research ethics, to highlight some neglected aspects (such as social responsibility), and to clarify some confusing ones (such as data management).
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.

Scientific fraud

“Fraud” is no longer widely used in this context. It was replaced by “misconduct in science” or “scientific misconduct” because most legal interpretations of the term “fraud” require evidence not only of intentional deception but also of injury or damage to victims. Proof of fraud in common law requires documentation of damage incurred by victims who relied on fabricated or falsified research results. Because this evidentiary standard seemed poorly suited to the methods of scientific research, “misconduct in science” has become the common term of reference in both institutional and regulatory policy definitions.11 (p.25)

Misconduct in science or research misconduct

A single Federal definition of research misconduct was proposed in October of 1999 and adopted December 6, 2000. “Misconduct” is a technical, semi-legal term designating behaviors that justify Federal intervention, and the precise definition is important.

1. Research* Misconduct Defined

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.**

Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

*Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

**The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.
II. Findings of Research Misconduct

A finding of research misconduct requires that:

There be a significant departure from accepted practices of the relevant research community; and

The misconduct be committed intentionally, or knowingly, or recklessly; and

The allegation be proven by a preponderance of evidence. 8 (p.76262)

The above definition replaces two existing definitions, one developed by the Public Health Service and the other by the National Science Foundation, with one single definition and policy. The two earlier definitions essentially boil down to “fabrication, falsification, plagiarism, or other serious deviation 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. 12 (p.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 kind against a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith.13 (p.22287)

In 1995, the Congressionally-appointed Commission on Research Integrity (a.k.a. the Ryan commission) submitted its report, Integrity and Misconduct in Research,14 proposing the following definition of misconduct, which was not adopted.

The Commission recommends that the Secretary replace the existing definition of misconduct in science with the definition of research misconduct and definitions of other forms of professional misconduct related to research, to follow. The definition of research misconduct is based on the premise that research misconduct is serious violation of the fundamental principle that scientists be truthful and fair in the conduct of research and the dissemination of its results.

The Federal Government has an interest in professional misconduct involving the use of federal funds in research, as covered by the following definitions:

1. Research Misconduct

Research misconduct is significant misbehavior that improperly appropriates the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record or compromising the integrity of scientific practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research, or in reviewing the proposals or research reports of others.
Examples of research misconduct include but are not limited to the following:

**Misappropriation:** An investigator or reviewer shall not intentionally or recklessly

a. plagiarize, which shall be understood to mean the presentation of the documented words or ideas of another as his or her own, without attribution appropriate for the medium of presentation; or

b. make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

**Interference:** An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.

**Misrepresentation:** An investigator or reviewer shall not with intent to deceive, or in reckless disregard for the truth,

a. state or present a material or significant falsehood; or

b. omit a fact so that what is stated or presented as a whole states or presents a material or significant falsehood.

Free scientific inquiry naturally includes proposing hypotheses that may ultimately prove to be false, offering interpretations of data that conflict with other interpretations, and making scientific observations and analyses that may prove to be in error. The Commission’s recommendations pose no threat to such inquiry, which is essential to the advancement of science.

The sanctionable behaviors defined and elaborated here are not intended to limit or define comprehensively the oversight role of academic and research institutions, which are free to adopt more demanding standards.14 (pp.13-14) emphases in original

**Other Forms of Professional Misconduct**

Immediately following its proposed definition of misconduct in research, *Integrity and Misconduct in Research* provides a definition of “Other Forms of Professional Misconduct,” as follows:

2. **Other Forms of Professional Misconduct**

a. **Obstruction of Investigations of Research Misconduct**

The Federal Government has an important interest in protecting the integrity of investigations into reported incidents of research misconduct. Accordingly, obstruction of investigations of research misconduct related to federal funding constitutes a form of professional misconduct in that it undermines the interests of the public, the scientific community, and the Federal Government.

Obstruction of investigations of research misconduct consists of intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; falsifying evidence; encouraging, soliciting or giving false testimony; and attempting to intimidate or retaliate against witnesses, potential witnesses, or potential leads to witnesses or evidence before, during, or after the commencement of any formal or informal proceeding.
b. Noncompliance with Research Regulations

Responsible conduct in research includes compliance with applicable federal research regulations. Such regulations include (but are not limited to) those governing the use of biohazardous materials and human and animal subjects in research.

Serious noncompliance with such regulations after notice of their existence undermines the interests of the public, the scientific community, and the Federal Government and constitutes another form of professional misconduct.

The Commission’s proposed definition of research misconduct and definitions of other forms of professional misconduct related to research will reach their full meaning when tested with real-world experience, cases, and commentaries. The Commission is relying on professional societies, research institutions, science ethics scholars, and case law to develop the interpretive context.14 (p.14, emphases in original)

Questionable research practices

In 1992, the Committee on Science, Engineering, and Public Policy (COSEPUP) of the National Academies proposed the concept of “questionable research practices” 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.11 (p.28)

Questionable research practices include activities such as the following:

- 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.11 (p.28)

Pathological science

A term coined by Irving Langmuir: “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.”15 (quoted in 16) Pathological science is a form of unintentional bias, usually used to describe incidents in which many researchers are
deluded by interesting or exciting – though erroneous – findings; examples often cited are polywater, N-rays, and cold fusion.

**Research integrity**

In some contexts, “research integrity” refers to the extent to which publicly presented research accurately reflects the scientific findings and is not tainted by fabrication or falsification. A wider definition was proposed by Nicholas Steneck: “a measure of the degree to which researchers adhere to the rules or laws, regulations, guidelines, and commonly accepted professional codes and norms of their respective research areas.”

**Regulatory compliance**

This term expresses concern with following the rules (regulations and laws), including the rules of a lab, research group, department, university, state, or country.

**Scientific ethics**

“Scientific ethics” is sometimes used to describe a subset of professional ethics – the professional ethics of scientists.

**Research ethics and the responsible conduct of research (RCR)**

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, judgmental, moralistic, or abstract.

**Appendix B: Details of the PHS Core Instructional Areas**

This appendix is quoted from the Office of Research Integrity’s *PHS Policy on Instruction in the Responsible Conduct of Research (RCR).*

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.

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