Short Course in Clinical Research

Responsible Conduct of Research

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Definitions

- **Research.** "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

- **Conduct of Research.** Conduct comprises the design, execution, and reporting of research.

- **Responsible.** We are all equally responsible for ensuring the ethically appropriate design, execution, and reporting of research.
Research Misconduct

• **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 differences of opinion.
201 Misconduct Cases

- **Type of misconduct**
  - Fabrication or falsification 120 (59.7%)
  - Plagiarism only 73 (36.3%)
  - Unknown 8 (4.0%)

- **Was it reported?**
  - Yes, reported by responder 49 (24.4%)
  - Yes, reported by someone else 67 (33.3%)
  - No, not reported 75 (37.3%)
  - Don’t know/No answer 10 (5.0%)


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Rank of Those Suspected*

- Professor or senior scientist 44 (21.9%)
- Associate professor or scientist 28 (13.9%)
- Assistant professor or scientist 34 (16.9%)
- Postdoctoral fellow 50 (24.9%)
- Graduate student 29 (14.4%)
- Other (includes 1 unknown) 24 (11.9%)

- Eight cases identified more than one person involved in incident

### Engaged in Behavior Past 3 yrs

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Falsifying or “cooking” research data</td>
<td>0.3%</td>
</tr>
<tr>
<td>Ignoring major aspects of human subjects requirements</td>
<td>0.3%</td>
</tr>
<tr>
<td>Failing to present data that contradict one’s own previous research</td>
<td>6.0%</td>
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<tr>
<td>Changing the design, methodology or results of a study in response to pressure from a funding sources</td>
<td>15.5%</td>
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<tr>
<td>Inappropriately assigning authorship credit</td>
<td>10.0%</td>
</tr>
<tr>
<td>Inadequate record keeping related to research projects</td>
<td>27.5%</td>
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Elements of RCR

- Research Misconduct
- Data Acquisition, Management, Sharing & Ownership
- Publication Practices and Responsible Authorship
- Human Subjects
- Animal Welfare
- Mentor/Trainee Responsibilities
- Collaborative Science
- Conflict of Interest & Commitment
- Peer Review
Sources of Rules for RCR

- Federal and State Laws and Regulations
- Professional Codes of Conduct
- Campus Policies and Guidelines
- Personal Values
- Moral Reasoning
Sources of Rules for RCR

- Planning Research
- Conducting Research
- Reporting Research

Topics in RCR

Planning Research
- Human Subjects
- Animal Welfare
- Conflict of Interest & Commitment

Conducting Research
- Data Acquisition, Management, Sharing & Ownership
- Mentor/Trainee Responsibilities
- Collaborative Science

Reporting Research
- Publication Practices and Responsible Authorship
- Peer Review

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Books & Articles I


Books & Articles II

http://info.gradsch.wisc.edu/research/wkshop/ethicscourses.html

- Oncology 675: Appropriate Conduct and Effective Communication of Science
- Nursing 802: Ethics and the Responsible Conduct of Research
- Surgical Sciences 812: Research Ethics and Career Development
- Bacteriology 901: Advanced Seminar: Responsible Conduct of Research
- Medical History & Bioethics 999: Research Ethics
Online Training

https://my.gradsch.wisc.edu/citi/index.php

- Collaborative Institutional Training Initiative
- User Name is UW Campus NetID
- Responsible Conduct of Research for Biomedical Researchers
- Responsible Conduct of Research for Social & Behavioral Science Researchers
Online Resources

- Office of Research Integrity (DHHS) www.ori.hhs.gov
- Online Ethics Center for Engineering and Science (Case Western) www.onlineethics.org
- Poynter Center for the Study of Ethics & American Institutions (Indiana) poynter.indiana.edu/index.shtm
- Responsible Conduct of Research (Boston College) www.bc.edu/research/rcip/rcr.html
- Responsible Conduct of Research Education Consortium (RCREC) rcrec.org
- Survival Skills and Ethics Program (Pittsburgh) www.survival.pitt.edu/index.asp

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Questions?
For More Information

Research Policy website:
http://info.gradsch.wisc.edu/research/policyrp/

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