Research Misconduct

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Definition of Research Misconduct

- 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 (i.e. the record of data or results that embody the facts emerging from the research, and includes, but is not limited to, research proposals, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and books).
- 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.
Findings of Research Misconduct

A finding of research misconduct requires that:

- there be a significant departure from accepted practices of the relevant research community (i.e. the humanities, social sciences, or scientific research community);
- the misconduct be committed intentionally, or knowingly, or recklessly; and
- the allegation be proven by a preponderance of evidence.
Responsibilities of Federal Agencies and Research Institutions

- Agencies and research institutions are partners who share responsibility for the research process. Federal agencies have ultimate oversight authority for Federally funded research, but research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.
Responsibilities of Federal Agencies and Research Institutions

- **Agency Policies and Procedures.** Agency policies and procedures with regard to intramural as well as extramural programs must conform to the policy described in this document.

- **Agency Referral to Research Institution.** In most cases, agencies will rely on the researcher’s home institution to make the initial response to allegations of research misconduct. Agencies will usually refer allegations of research misconduct made directly to them to the appropriate research institution. However, at any time, the Federal agency may proceed with its own inquiry or investigation. Circumstances in which agencies may elect not to defer to the research institution include, but are not limited to, the following: the agency determines the institution is not prepared to handle the allegation in a manner consistent with this policy; agency involvement is needed to protect the public interest, including public health and safety; the allegation involves an entity of sufficiently small size (or an individual) that it cannot reasonably conduct the investigation itself.
Multiple Phases of the Response to an Allegation of Research Misconduct

A response to an allegation of research misconduct will usually consist of several phases, including:

1. An **inquiry** – the assessment of whether the allegation has substance and if an investigation is warranted
2. An **investigation** – the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies
3. The **adjudication** – during which recommendations are reviewed and appropriate corrective actions determined.
Agency Follow-up to Institutional Action

- After reviewing the record of the investigation, the institution’s recommendations to the institution’s adjudicating official, and any corrective actions taken by the research institution, the agency will take additional oversight or investigative steps if necessary. Upon completion of its review, the agency will take appropriate administrative action in accordance with applicable laws, regulations, or policies. When the agency has made a final determination, it will notify the subject of the allegation of the outcome and inform the institution regarding its disposition of the case. The agency finding of research misconduct and agency administrative actions can be appealed pursuant to the agency’s applicable procedures.
Agency Administrative Actions

Administrative actions available include, but are not limited to,

- appropriate steps to correct the research record
- letters of reprimand
- the imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of an award
- suspension or termination of an active award
- or suspension and debarment in accordance with applicable government-wide rules on suspension and debarment.
Cases of Criminal or Civil Fraud Violations

- If the funding agency believes that criminal or civil fraud violations may have occurred, the agency shall promptly refer the matter to the Department of Justice, the Inspector General for the agency, or other appropriate investigative body.
Government Shutdowns
The Compliance Officer’s Nightmare !!

- Massachusetts Eye and Ear Infirmary
- UCLA
- VA Health Sys Greater Los Angeles
- Rush Presbyterian St Luke’s Med Ctr
- University of Illinois Chicago
- Duke University Med Ctr
- Univ Texas Medical Branch Galveston
- University of Oklahoma Tulsa
- Johns Hopkins University
Study Death, Other Problems Discovered at Detroit, Fargo VA Research Programs

Vermont Reseach Manager Who Lied Admits Submitting False Data in Clinical Study Gets Probation, Small Fine

Fraudulent Statements in Research Admits Submitting Data in Intent Applications

Garner Most Trouble, DOJ Enforcer Says

More Than One-Third of U.S. Scientists Admit to Conduct, Survey Says
## Highly Visible Patients Deaths

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Year</th>
<th>Type of Trial</th>
<th>Location</th>
<th>Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tony LaMadrid</td>
<td>1991</td>
<td>Schizophrenia</td>
<td>UCLA</td>
<td>Government</td>
</tr>
<tr>
<td>Kathryn Hamilton</td>
<td>1993</td>
<td>Breast Cancer</td>
<td>Hutchinson Cancer Center</td>
<td>Industry</td>
</tr>
<tr>
<td>Nicole Wan</td>
<td>1996</td>
<td>Airborne Chemicals</td>
<td>Univ of Rochester, MIT-sponsored</td>
<td>Government</td>
</tr>
<tr>
<td>Three Children</td>
<td>1998</td>
<td>Leukemia</td>
<td>St. Jude Children’s Hospital, Memphis</td>
<td>Government</td>
</tr>
<tr>
<td>Gage Stevens</td>
<td>1999</td>
<td>Acid Reflux</td>
<td>Children’s Hospital, Pittsburgh</td>
<td>Government</td>
</tr>
<tr>
<td>Jesse Gelsinger</td>
<td>1999</td>
<td>Gene Therapy</td>
<td>Univ of Pennsylvania</td>
<td>Government</td>
</tr>
<tr>
<td>Ellen Roche</td>
<td>2001</td>
<td>Asthma</td>
<td>Johns Hopkins</td>
<td>Government</td>
</tr>
</tbody>
</table>

SSKR&P, Bioethics Issue, 2001
“focused attention on the process by which patients come to participate in studies testing the safety and efficacy of new therapies... The process of informed consent is inherently flawed. Ill patients are too desperate to read the consent form carefully and ask all of the questions they need to ask, while investigators fail to provide balanced descriptions of the experimental process because...they may have vested interests in persuading patients to participate in studies”

*Lawrence K. Altman* of *The New York Times*
“Scientists need additional oversight, because they are too optimistic about the possibilities for a cure and failed to think skeptically about the data they collect”

*David Kessler former head of the FDA*
Case 1

University of Vermont Researcher
Case 2

Crossing the Line: Research/Criminal
In the seven cancer studies they conducted together, Holland, Kornak, or both altered medical records to conceal kidney disease, cancer surgeries, and severe heart problems, including a possible heart attack, according to a Food and Drug Administration inspection report obtained by BNA. Blood chemistries, cancer bone scans, echocardiograms, prostate cancer checks, and other necessary tests were not performed, though study records indicated they had been, the report said. Tests that were done had dates and results altered. Drugs were given in wrong doses and, in one case, patients already hard of hearing got a medication that could make hearing worse, FDA found.

The altered records made patients appear sicker or healthier than they actually were, so that they could be enrolled in drug studies for which they would not otherwise have qualified. Consequently, subjects were given drugs they should not have gotten, in ways their makers had not intended them to be administered, the inspectors concluded.

VA investigators separately have concluded the actions probably caused one death and may have caused at least four more. An ongoing federal criminal investigation could bring murder charges (2 MRLR 132, 2/19/03).

Stratton officials hired Kornak to recruit for and monitor patients in sensitive cancer studies despite knowing his medical license had been revoked in two states, a move that implicates the federal government in negligence, Milstein said.
Auditing Human Research Protections: Structuring the Audit

Focus on Common Compliance Problems
• IRB
• Clinical Investigator

Resources
• FDA
  – Information Sheets
  – Checklist
• OHRP
  – Compliance Concerns
  – QA/QI Program
Enforcement of FDA Regulations

- Office of Good Clinical Practice
  - Within Office of Science Coordination & Communication
  - Within Office of Commissioner
    - [http://www.fda.gov/oc/gcp](http://www.fda.gov/oc/gcp)

- Bioresearch Monitoring Program
  - Within Office of Regulatory Affairs

- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiologic Health (CDRH)
Enforcement of FDA Regulations: Bioresearch Monitoring Program

- On-site inspections and data audits to monitor all aspects of FDA regulated research
  - Clinical Investigations (GCPs)
  - Institutional Review Boards (IRBs)
  - Nonclinical Labs (GLPs)
- Assure the quality and integrity of data
- Protect rights and welfare of human subjects
- 1000+ domestic and international audits yearly
- Warning Letters: [www.fda.gov/foi/warning.htm](http://www.fda.gov/foi/warning.htm)
OHRP & FDA Compliance Determinations

OHRP Survey
FDA Warning Letters
OHRP Action

In view of the above determinations and in order to ensure adequate protections for human subjects at the covered institutions, in accordance with HHS regulations at 45 CFR 46.103, OHRP hereby suspends the Multiple Project Assurance.

As result, all Federally supported research projects at the covered institutions must be suspended. For any project affected by this suspension, enrollment of new subjects must cease immediately except in extraordinary cases approved in advance by OHRP (OHRP would expect requests for such approvals to be rare). Furthermore, research activities involving previously enrolled subjects may continue only where it is in the best interests of individual subjects. No suspended Federally supported research at these institutions may resume without OHRP reinstatement of the MPA, or approval by OHRP of an applicable Assurance.
OHRP Compliance Determinations: Letters Issued 10/01/1998 to 06/30/2002

- 269 Letters to 155 Institutions
- 18 Institutions Site-Visited
- 1,120 Citations of Noncompliance or Deficiency
- 142 Institutions (92%) Had at Least One Citation
  - Median = 4
  - Range: 0 - 53
OHRP Compliance Findings: Informed Consent Deficiencies

Informed Consent Must:

- Be Legally Effective
  - Federal Regulations
  - Applicable State Law (who is legally authorized representative)
- Be In Language Understandable to the Subject
- Be Free of Coercion or Undue Influence
- Be Free of Exculpatory Language (broadly defined)
- Include Eight required elements
- Include Six additional elements
Note similarity to OHRP Findings:
- Written Policies and Procedures
- Documentation of IRB Actions
- Initial or Continuing Review
- Expedited IRB review procedures
The purpose of this letter is to inform you of objectionable practices and activities found during a Food and Drug Administration (FDA) inspection of

Based on the deficiencies found during this inspection, the IRB does not meet the requirements of 21 CFR Part 56. We have no assurance that your IRB procedures are adequately protecting the rights, safety, and welfare of the human subjects of research. For this reason, in accordance with 21 CFR 56.120(b)(1) and 56.103(a), and effective immediately, no new studies that are subject to Parts 50 and 56 of the FDA regulations are to be approved by your IRB. This restriction will remain in effect until you are notified in writing by FDA that the IRB's corrective actions are satisfactory, that the IRB meets the requirements of Part 56, and that the restrictions have been removed.

We will review your response and determine whether the actions are adequate to permit the IRB to resume unrestricted activities. Your failure to adequately respond to this letter may result in further administrative actions against your IRB, as authorized by 21 CFR 56.120 and 121. These actions include initiating regulatory proceedings for disqualification of your IRB.
FDA: Clinical Investigator Deficiencies
250-300 CI Inspections/Year 1980 – 1999

- Protocol Adherence
- Documentation/Records
- Adverse Event Reporting
- Drug Accountability
- Informed Consent
WARNING LETTER

Alkis Togias, M.D.
Johns Hopkins Asthma & Allergy Center
5501 Hopkins Bayview Circle
Baltimore, Maryland 21224

investigation into the death of a healthy volunteer who had received the drug, hexamethonium bromide, in the study, "Mechanisms of Deep Inspiration-Induced Airway Relaxation," Protocol[ ] in which you participated as a sponsor and an investigator. Our personnel presented and discussed Form FDA 483, Inspectional

concludes that you violated the Federal Food, Drug, and Cosmetic Act (the Act) and FDA regulations governing the use of investigational new drugs by initiating a clinical investigation subject to 21 CFR Part 312 without submitting an investigational new drug application (IND). CDER also concludes that you failed to meet the obligations of a sponsor and an investigator under applicable regulations as noted below.
Our records indicate that you are aware of your sponsor obligations under 21 CFR 312.23 in that you have been the sponsor of at least one IND application. In particular, we note that on September 15, 1997, you submitted an IND application to the FDA that proposed to use capsaicin to study the neuronal mechanism of allergic and non-allergic reactions in the nasal and tracheobronchial mucosa of human subjects. The Division of Pulmonary Drug Products (DPDP) notified you in writing on October 24, 1997, that you were prohibited from initiating any of the submitted protocols due to significant safety concerns and other protocol deficiencies (21 CFR 312.42(b)). The letter from DPDP included a detailed list of deficiencies, including inadequate chemistry, purity, and preclinical data; inadequate and confusing study procedures and protocols; lack of inclusion criteria, discontinuation criteria, and defined safety parameters; and lack of methodology for adverse event monitoring, treatment, and follow-up of subjects.
2. VIOLATIONS RELATED TO CONDUCT OF THE STUDY UNDER AN IND (21 CFR 312.20).

You failed to submit an IND for the conduct of a clinical investigation with an investigational new drug as required by 21 CFR 312.20(a).

A clinical investigation is defined as "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects... except for the use of a marketed drug in the course of medical practice." (21 CFR 312.3). You conducted a study in which you administered a drug not approved for marketing (hexamethonium bromide) to human subjects, and accordingly, conducted a clinical investigation.

4. VIOLATIONS RELATED TO INVESTIGATOR RESPONSIBILITIES AND ASSURANCE OF IRB REVIEW (21 CFR 312.60 AND 312.66).

a. You failed to notify and obtain IRB approval as required by 21 CFR 312.66 for the following changes in research activity:

1. The change in the dosing conditions for the administration of hexamethonium bromide, including changes to the delivery system and the rate of administration.

2. The addition of sodium bicarbonate to the hexamethonium bromide prior to its use in subjects[---]and[---](the third subject).

3. The change in formulation of the hexamethonium bromide solution, from normal saline to distilled water, and change in formulation of the vehicle control solution, from normal saline to hyperosmolar saline.
b. You failed to protect the safety and welfare of subjects under your care as required by 21 CFR 312.60 in that you failed to promptly report to the IRB the following unanticipated problems involving risk to human subjects as required by 21 CFR 312.66:

1. Subject [____] received hexamethonium bromide on 4/23/01, and developed persistent cough and dyspnea (shortness of breath) from 4/25/01 to 5/3/01.

2. Subject [____] received hexamethonium bromide on 4/27/01 and experienced fatigue, mild ptosis and a 36% fall in FEV₁. Subject [____] received hexamethonium bromide again on 5/1/01, and experienced a 10-mm/Hg decrease in blood pressure, a pulse increase of 25 beats per minute, lightheadedness, ptosis, and a 42% fall in FEV₁. On each occasion, you deemed it necessary to discontinue the study visit.


You failed to obtain proper informed consent in that the following essential elements of informed consent were not included in the consent form that was provided to the healthy volunteers:

a. The consent form failed to disclose that the inhalation of hexamethonium bromide was an experimental use of the drug.

b. The consent form represented hexamethonium bromide as a medication and failed to disclose that the hexamethonium bromide used would be chemical grade, labeled for laboratory use only and not for drug use. The labeling also stated: “do not breathe dust…may be harmful if inhaled.”
c. The consent form failed to disclose the risk of lung toxicity and death in recipients of chronic therapy with hexamethonium salts by oral and intravenous routes.

d. The consent form failed to disclose the fact that systemic absorption of inhaled hexamethonium bromide could result in a wide range of adverse events resulting from ganglionic blockade.

c. The consent form was not updated to include the unexpected adverse events experienced by the first two subjects in the study.

After observing the unexpected respiratory symptoms experienced by the first subject, you were required to update the consent form for the two subsequent subjects, and to inform them of the risk of these unexpected adverse events. You were also required to inform subject the third subject, that subject required early discontinuation of the study drug on two occasions after administration of hexamethonium bromide.

Within fifteen (15) working days of receipt of this letter, you must notify this office in writing of the specific corrective actions you have taken or will be taking to address these deficiencies and to achieve compliance with FDA regulations. We will review your response and determine whether the actions are adequate. As one way to achieve compliance, we recommend that you consider entering into the attached restricted agreement with the agency regarding your future use of investigational new drugs. Please note that failure to correct deficiencies may result in regulatory action without further notice.

Sincerely yours,

Joanne L. Rhoads, M.D.
Joanne L. Rhoads, M.D., MPH
Director
Division of Scientific Investigations, HFD-45
Office of Medical Policy
Center for Drug Evaluation and Research
Resource List

- Office for Human Research Protections (OHRP)
- Office of Research Integrity (ORI)
- Association American of American Medical Colleges
- Clinical Trials Advisor
- Clinical Trials.gov
- Center Watch.com
Resource List

- Academic Medical Centers (AMC)
- Food and Drug Administration
  - [http://www.FDA.gov](http://www.FDA.gov)
- Center for Medicaid & Medicare Services
- Guidance for Industry: Good Clinical Practice: Consolidated Guidance
- National Institutes of Health
  - [http://www.NIH.gov](http://www.NIH.gov)
- Institute of Medicine
  - [http://www.iom.edu/](http://www.iom.edu/)
Guidance and Reports

—DHHS Draft Guidance:

—AAMC Report:

—GAO Report:

—AAU Report:
  - http://www.aau.edu/research/COI.01.pdf

—AMA Report:
  - Available upon request (email: ceja@ama-assn.org)
<table>
<thead>
<tr>
<th>Cited Deficiency</th>
<th>All Institutions (N = 155)</th>
<th>Site-Visited Institutions (N = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research conducted without IRB review</td>
<td>17%</td>
<td>22%</td>
</tr>
<tr>
<td>Deficiency in IRB initial review process</td>
<td>55%</td>
<td>94%</td>
</tr>
<tr>
<td>Deficiency in IRB continuing review process</td>
<td>45%</td>
<td>72%</td>
</tr>
<tr>
<td>Deficiency in use of expedited IRB review procedure</td>
<td>17%</td>
<td>61%</td>
</tr>
<tr>
<td>Deficiency in satisfying reporting requirements</td>
<td>17%</td>
<td>39%</td>
</tr>
<tr>
<td>Deficiency in IRB review of protocol changes</td>
<td>25%</td>
<td>39%</td>
</tr>
<tr>
<td>Deficiency in application of exempt categories of research</td>
<td>6%</td>
<td>28%</td>
</tr>
<tr>
<td>Failure to obtain informed consent of subjects</td>
<td>16%</td>
<td>11%</td>
</tr>
<tr>
<td>Deficiency in documentation of informed consent</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Deficiency in IRB-approved informed consent docs/process</td>
<td>51%</td>
<td>78%</td>
</tr>
<tr>
<td>Deficiency in IRB membership</td>
<td>11%</td>
<td>61%</td>
</tr>
<tr>
<td>IRB members lack sufficient understanding of regulations</td>
<td>7%</td>
<td>44%</td>
</tr>
<tr>
<td>Indequate IRB meeting space, staff, and resources</td>
<td>8%</td>
<td>50%</td>
</tr>
<tr>
<td>Overburdened IRB</td>
<td>5%</td>
<td>28%</td>
</tr>
<tr>
<td>Deficiency in IRB records, including IRB minutes</td>
<td>37%</td>
<td>78%</td>
</tr>
<tr>
<td>Deficiency in written IRB policies and procedures</td>
<td>55%</td>
<td>72%</td>
</tr>
</tbody>
</table>
### OHRP Compliance Oversight Data - 10/1998 to 6/2002

**Distribution of Noncompliance Findings (269 Letters)**

Table 2: Distribution of OHRP-Cited Deficiencies for All Institutions

<table>
<thead>
<tr>
<th>Category of Deficiency</th>
<th>Number of Citations</th>
<th>Percent of Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deficiency in IRB initial review process</td>
<td>277</td>
<td>25%</td>
</tr>
<tr>
<td>Deficiency in IRB-approved informed consent documents/process</td>
<td>304</td>
<td>27%</td>
</tr>
<tr>
<td>Deficiency in IRB continuing review process</td>
<td>109</td>
<td>10%</td>
</tr>
<tr>
<td>Deficiency in written IRB policies and procedures</td>
<td>88</td>
<td>8%</td>
</tr>
<tr>
<td>Deficiency in IRB records, including IRB minutes</td>
<td>70</td>
<td>6%</td>
</tr>
<tr>
<td>Deficiency in IRB membership/training/support/workload</td>
<td>49</td>
<td>4%</td>
</tr>
<tr>
<td>Deficiency in IRB review of protocol changes</td>
<td>45</td>
<td>4%</td>
</tr>
<tr>
<td>Deficiency in use of IRB expedited review procedure</td>
<td>46</td>
<td>4%</td>
</tr>
<tr>
<td>Deficiency in satisfying reporting requirements</td>
<td>35</td>
<td>3%</td>
</tr>
<tr>
<td>Research conducted without IRB approval</td>
<td>25</td>
<td>2%</td>
</tr>
<tr>
<td>Failure to obtain informed consent of subjects</td>
<td>26</td>
<td>2%</td>
</tr>
<tr>
<td>Other miscellaneous deficiencies</td>
<td>46</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1120</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
### OHRP Compliance Oversight Data - 10/1998 to 6/2002

#### Distribution of Noncompliance Findings (269 Letters)

**Table 3: Distribution of OHRP-Cited Deficiencies Related to Initial IRB Review**

<table>
<thead>
<tr>
<th>Category of Deficiency in IRB Initial Review</th>
<th>Number of Citations</th>
<th>Percent of Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deficiency related to criteria required for IRB approval</td>
<td>88</td>
<td>32%</td>
</tr>
<tr>
<td>Deficiency related to findings for research involving children</td>
<td>39</td>
<td>14%</td>
</tr>
<tr>
<td>Contingent approval with substantive changes/clarifications without further review by convened IRB</td>
<td>33</td>
<td>12%</td>
</tr>
<tr>
<td>Deficiency related to findings for waiver of informed consent requirements</td>
<td>30</td>
<td>11%</td>
</tr>
<tr>
<td>IRB review without quorum</td>
<td>25</td>
<td>9%</td>
</tr>
<tr>
<td>Failure to review federal grant applications</td>
<td>16</td>
<td>6%</td>
</tr>
<tr>
<td>Deficiency related to findings for research involving prisoners</td>
<td>14</td>
<td>5%</td>
</tr>
<tr>
<td>Other miscellaneous deficiencies</td>
<td>32</td>
<td>12%</td>
</tr>
<tr>
<td>Total</td>
<td>277</td>
<td>100%</td>
</tr>
</tbody>
</table>
### Distribution of OHRP-Cited Deficiencies Related to Informed Consent

#### Table 4: Distribution of OHRP-Cited Deficiencies Related to Informed Consent

<table>
<thead>
<tr>
<th>Category of Deficiency Related to Informed Consent</th>
<th>Number of Citations</th>
<th>Percent of Citations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deficiency in description of purpose, procedures, and duration</td>
<td>63</td>
<td>19%</td>
</tr>
<tr>
<td>Deficiency in description of risks and discomforts</td>
<td>56</td>
<td>17%</td>
</tr>
<tr>
<td>Deficiency in description of benefits</td>
<td>20</td>
<td>6%</td>
</tr>
<tr>
<td>Deficiency in description of alternatives</td>
<td>20</td>
<td>6%</td>
</tr>
<tr>
<td>Deficiency in description of other elements of informed consent</td>
<td>61</td>
<td>18%</td>
</tr>
<tr>
<td>Language too complex</td>
<td>31</td>
<td>9%</td>
</tr>
<tr>
<td>Use of exculpatory language</td>
<td>7</td>
<td>2%</td>
</tr>
<tr>
<td>Failure to obtain informed consent of subjects</td>
<td>26</td>
<td>8%</td>
</tr>
<tr>
<td>Deficiency in documentation of informed consent</td>
<td>12</td>
<td>4%</td>
</tr>
<tr>
<td>Other miscellaneous deficiencies</td>
<td>34</td>
<td>10%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>330</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
References

2. PRIM&R, *2003 Annual IRB Conference Administrator 101 Resources*