

BT 623: Research Methodology

Lecture 21: Ethics (*cont...*)



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A. Autonomy (Self-determination)/ Informed Consent/Right to Refuse Treatment

Schloendorff v. Society of New York Hospital. 211 N.Y. 125, 105 N.E. 92 (1914).

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." That opinion by Justice Benjamin N. Cardozo became the foundation for the right to self-determination, which underlies the principle of respect for autonomy in bioethics. Mary Schloendorff had agreed only to an examination of a fibroid tumor, which had to be done under ether. She notified one of her doctors that she did not want an operation. While she was anesthetized, the doctors removed a tumor. Postsurgical complications involved gangrene in her left arm and resulted in the amputation of some fingers. Unlike most preceding cases of alleged negligence on the part of doctors, Schloendorff's case was the first to be based on a claim of trespass or unlawful interference with her body. Cardozo noted exceptions to the right to self-determination "in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained."

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https://repository.library.georgetown.edu/bitstream/handle/10822/556889/Susan%20Cartier%20Poland%20-%20Landmark%20Legal%20Cases%20in%20Bioethics%20-%20Kennedy%20Institute%20of%20Ethics%20Journal%207_2.pdf?sequence=4&isAllowed=y

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Salgo v. Leland Stanford Jr. University Board of Trustees. 154 Cal. App. 2d 560, 317 P.2d 170 (1957).

The term "informed consent" was first used in the *Salgo* case. Martin Salgo, age 55, suffered from arteriosclerosis and was advised to undergo diagnostic aortography. He was put under anesthesia, his aorta was injected with an X-ray contrast medium, and X-rays were taken of the blocked abdominal aorta. The next morning Salgo discovered that his lower limbs were paralyzed. The court noted that a physician violates his duty to the patient if he withholds any facts necessary to form the basis of an intelligent consent **[End Page 193]** by the patient to the proposed treatment. The court also noted that when discussing risk, the physician has discretion "consistent with the full disclosure of facts necessary to an informed consent."

C. Confidentiality (Physician-Patient Relationship/Third Parties)

Tarasoff v. Regents of the University of California. 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (1976).

Tarasoff is the preeminent case on physician-patient confidentiality and the duty to warn third parties. Two months before university student Prosenjit Poddar murdered another university student, Tatiana Tarasoff, outside her family home, he had told his psychologist at the university hospital of his intent to kill her. At the psychologist's request, university police had detained Poddar, but only briefly because he appeared to be rational. "When a therapist determines, or pursuant to the standards of his profession should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to protect the intended victim against such danger." This may entail warning the victim or notifying the police, or "whatever steps are reasonably necessary under the circumstances." No one in the Tarasoff family had been notified of the danger. Furthermore, disclosure of confidential physician-patient communication when it is essential to prevent danger to others must be done "discreetly," to protect the patient's privacy "to the fullest extent compatible with the prevention of the threatened danger."

D. Public Health (Vaccination/Sterilization)

Jacobson v. Massachusetts. 197 U.S. 11, 25 S. Ct. 358, 49 L. Ed. 463 (1905).

Under the police power of the state, compulsory vaccination does not violate an individual's liberty interest under the Fourteenth Amendment. Because both he and his son had had adverse reactions to the smallpox vaccine, Jacobson refused to be revaccinated as required by a local ordinance of Cambridge, Massachusetts. That statute exempted a child but not an adult from vaccination if a physician's certificate were provided. The Court held under the principle of self-defense, "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members." Persons and property are subject to reasonable government restraints and burdens as deemed to be "essential to the safety, health, peace, good order and morals of the community." "[G]overnment is instituted 'for the common good, for the protection, safety, prosperity and happiness of the people, and not for the profit, honor or private interests of any one man, family or class of men.'"

Buck v. Bell. 274 U.S. 200, 47 S. Ct. 584, 71 L. Ed. 1000 (1927).

"Three generations of imbeciles are enough," wrote Justice Oliver Wendell Holmes about the case of Carrie Buck. **[End Page 200]** Age 18, mentally retarded, and institutionalized, Buck was the daughter of a mentally retarded woman, who lived in the same state institution, and was herself the mother of an illegitimate mentally retarded child. The Commonwealth of Virginia sought sexual sterilization of Buck by salpingectomy, the cutting of the fallopian tubes, where fertilization takes place, an operation that would not affect her general health. The case arose under the constitutional issues of due process and equal protection of the Fourteenth Amendment. The Court rationalized that where public welfare often demanded the lives of the state's best citizens, not to ask a lesser sacrifice of one dependent on the state would be strange. The principle behind compulsory vaccination was broadly applied to support sexual sterilization.

E. Property (Person/Embryo/Body Parts)

York v. Jones. 717 F.Supp. 421 (E.D. Va. 1989).

Possession of cryogenically preserved embryos by an *in vitro* fertilization laboratory and the duty of the lab to account for the embryos creates a bailment (delivery of property in trust to another for a special purpose and for a limited period) relationship between the laboratory and the infertile couple. Steven York and Risa Adler-York wanted the Jones Institute to release their cryogenically preserved embryos for transfer to another *in vitro* fertilization lab for subsequent thawing and implantation. The lab refused to authorize release for transfer. The trial court found under contract law that in the cryopreservation agreement the lab recognized the Yorks' property rights to the embryos and had limited its own control over them.

G. Patenting (Invention/Creation)

In re Arzberger. 112 F.2d 834 (C.C.P.A. 1940).

A precursor to the issue of patenting organisms, the *Arzberger* decision is known for its ruling that the Plant Patent Act of 1930 does not encompass bacteria. The Court of Customs and Patent Appeals noted that although bacteria have characteristics of both plants and animals and the scientific authorities classify bacteria as plants, the legislative intent of Congress--and the controlling use--of the word "plant" was its common or popular sense, as tree, shrub or herb, or slip, cutting, or sapling.

Funk Brothers Seed Co. v. Kalo Inoculant Co. 333 U.S. 127, 68 S. Ct. 440, 92 L. Ed. 588 (1948).

The U.S. Supreme Court ruled in *Funk* that "aggregation of species" of bacteria into one product that has the same effect that each of the species has always had is not invention under patent law. Rhizobia bacteria infect the roots of legumes, like peas and beans, and become nodules, thus allowing the plants to affix nitrogen from the air. Different crops require different bacteria. The general practice was to sell inoculants with one species of the rhizobia bacteria, but Bond, the patent applicant, had created an inoculant with a mixed culture of several species. For a product to be patentable, it must be more than "new and useful;" it must also be a product of "invention or discovery." Packaging bacteria into one inoculant was a product of skill, not invention. "If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end," because "patents cannot issue for the discovery of nature."

Case Summaries

This page contains cases in which administrative actions were imposed due to findings of research misconduct. The list only includes those who CURRENTLY have an imposed administrative actions against them. It does NOT include the names of individuals whose administrative actions periods have expired. Each case is categorized according to the year in which ORI closed the case.

2024

[Case Summary: Bhan, Arunoday K.](#)
[Case Summary: Brigidi, Gian-Stefano](#)
[Case Summary: Eckert, Richard L.](#)
[Case Summary: Mousa, Shaker](#)
[Case Summary: Nguyen, Darrion](#)

2023

[Case Summary: Armstead, William M.](#)
[Case Summary: Dannenberg, Andrew J.](#)
[Case Summary: Frech, Ivana](#)
[Case Summary: He, Johnny J.](#)
[Case Summary: Hwa, Lara S.](#)
[Case Summary: Jayawardena, Surangi \(Suranji\)](#)
[Case Summary: Laliotis, Yiorgos \(Georgios\) I.](#)
[Case Summary: Martin, Sarah Elizabeth](#)
[Case Summary: Spirli, Carlo](#)
[Case Summary: Subbaramaiah, Kotha](#)

2022

[Case Summary: Brand, Toni M.](#)
[Case Summary: Chang, Alice C.](#)
[Case Summary: Jarrett, Stuart G.](#)
[Case Summary: Jiang, Janina](#)
[Case Summary: Leong, Daniel](#)
[Case Summary: Majumdar, Ritankar](#)
[Case Summary: Sun, Hui Bin](#)
[Case Summary: Taylor, Douglas D.](#)

2021

[Case Summary: Lin, Yibin](#)
[Case Summary: Wang, Ya](#)

2020

[Case Summary: Downs, Charles A.](#)
[Case Summary: Nemani, Prasadarao](#)
[Case Summary: Wang, Zhiwei](#)

2019

[Case Summary: Potts Kant, Erin N.](#)

2018

[Case Summary: Murthy, Krishna H.M.](#)

2008 and Older

[Case Summary: Kornak, Paul H.](#)
[Case Summary: Poehlman, Eric T.](#)
[Case Summary: Sudbo, Jon](#)

[Contact Us](#)

Case Summary: Bhan, Arunoday K.

Arunoday K. Bhan, Ph.D., Boston Children's Hospital, Harvard Medical School and City of Hope Medical Center: Based on the report of an investigation conducted by Harvard Medical School (HMS) and City of Hope Medical Center (COH) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that Arunoday K. Bhan, Ph.D. (Respondent), who was formerly a Research Fellow, Department of Pediatrics, Boston Children's Hospital, HMS, and a former Staff Scientist, Department of Surgery, COH, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant T32 HL066987. The questioned research was included in two grant applications submitted for PHS funds, specifically R03 CA270990-01 and R21 CA272364-01 submitted to the National Cancer Institute (NCI), NIH.

ORI found that Respondent engaged in research misconduct by intentionally and knowingly falsifying, fabricating, and/or plagiarizing data in the following one (1) published paper and two (2) grant applications:

- Human induced pluripotent stem cell-derived platelets loaded with lapatinib effectively target HER2+ breast cancer metastasis to the brain. *Sci Rep.* 2021 Oct 15;11(1):16866. doi: 10.1038/s41598-021-96351-2 (hereafter referred to as *Sci Rep.* 2021). Retraction in: *Sci Rep.* 2024 Mar 12;14(1):5972. doi: 10.1038/s41598-024-56291-z.
- R03 CA270990-01, "Human induced pluripotent stem cell derived platelets and platelet derived extracellular vesicles mediated delivery of chemotherapeutics for breast to brain metastasis treatment," submitted to NCI, NIH, on June 15, 2021 (hereafter referred to as R03 CA270990-01).
- R21 CA272364-01, "Off-the-shelf engineered human induced pluripotent stem cell derived platelets mediated delivery of HER2 inhibitors for HER2+ Breast to brain metastasis tumors immunotherapy," submitted to NCI, NIH, on September 29, 2021 (hereafter referred to as R21 CA272364-01).

Specifically, ORI found that Respondent intentionally and knowingly falsified, fabricated, and/or plagiarized:

- Figure 2D of *Sci Rep.* 2021, Figure 4A of R03 CA270990-01, and Figure 4A of R21 CA272364-01 by relabeling the transmission electron microscopy (TEM) image as Lapatinib-loaded platelet derived from the commercially available human induced pluripotent stem cell (hiPSC) line DF-19-9-7T when it was actually from a non-drug loaded platelet derived from a human donor sample, without appropriate citation to the researcher who generated the image
- Supplementary Figure SIB of *Sci Rep.* 2021 by relabeling the fluorescence microscopy images as from a culture of the hiPSC line DF-19-9-7T when these were actually from a derivative of the hiPSC line 1157.2, without appropriate citation to the researcher who generated the image
- Supplementary Figure SIE of *Sci Rep.* 2021 by relabeling the TEM image as from a megakaryocyte on day 6 of maturation obtained directly by differentiation of the hiPSC line DF-19-9-7T when it was actually from an immortalized megakaryocyte cell line (four days after doxycycline-withdrawal induction of differentiation) previously derived from hiPSC line 1156
- Supplementary Figure S1C of *Sci Rep.* 2021 by relabeling the karyotype image as from the hiPSC line DF-19-9-7T when it was actually from the hiPSC line 1156, without appropriate citation to the researcher who generated the image

H.M. Krishna Murthy, Ph.D., University of Alabama at Birmingham: Based on evidence and findings of an investigation conducted by the University of Alabama at Birmingham (UAB), the Office of Research Integrity's (ORI's) review of UAB's investigation, and additional evidence obtained and analysis conducted by ORI in its oversight review of UAB's investigation, ORI found that Dr. H.M. Krishna Murthy (Respondent), former Research Associate Professor, Department of Vision Sciences, UAB, committed research misconduct in research supported by PHS grants, specifically NIAID, NIH, grants R01 AI051615, R01 AI032078, and R01 AI045623; NHLBI, NIH, grants P01 HL034343 and R01 HL064272; and NIDDK, NIH, grant R01 DK046900.

Falsified and/or fabricated research was reported in:

- Nature 444:221-225, 2006 (hereafter referred to as "Nature 2006"); retracted in: Nature 532:268, 2016 April 14
- J. Biol. Chem. 274:5573-5580, 1999 (hereafter referred to as "J. Biol. Chem. 1999"); retracted in: J. Biol. Chem. 284:34468, 2009
- Proc. Natl. Acad. Sci. USA 101:8924-8929, 2004 (hereafter referred to as "PNAS 2004"); Editorial Expression of Concern in: PNAS 107:6551, 2010 April 6
- Biochem. 44:10757-10765, 2005 (hereafter referred to as "Biochem. 2005")
- Proc. Natl. Acad. Sci. USA 103:2126-2131, 2006 (hereafter referred to as "PNAS 2006"); Editorial Expression of Concern in: PNAS 107:6551, 2010 April 6
- Acta Cryst. D55:1971-1977, 1999 (hereafter referred to as "Acta Cryst. 1999"); retracted in: Acta Cryst. D66:222, 2010
- J. Mol. Biol. 301:759-767, 2000 (hereafter referred to as "J. Mol. Biol. 2000"); retracted in: J. Mol. Biol. 397:1119, 2010
- Cell 104:301-311, 2001 (hereafter referred to as "Cell 2001")
- Biochem. 41:11681-11691, 2002 (hereafter referred to as "Biochem. 2002")
- Protein Data Bank (PDB) identification codes 2HR0, 1BEF, 1RID, 1Y8E, 2A01, 1CMW, 2QID, 1DF9, 1G40, 1G44, 2OU1, and 1L6L (the PDB is funded in part by NIH)

Falsified and/or fabricated research results also were referenced in the following PHS grant applications:

- 1 R21 AI056224-01 submitted to NIAID, NIH
- 1 R01 AI064509-01 submitted to NIAID, NIH
- 1 R01 AI64509-01A1 submitted to NIAID, NIH
- 1 R01 AI051615-01A1 submitted to NIAID, NIH
- 1 R03 TW006840-01 submitted to Fogarty International Center (FIC), NIH

ORI found by a preponderance of the evidence that Respondent intentionally, knowingly, or recklessly engaged in research misconduct by falsifying and/or fabricating X-ray crystallographic data for eleven (11) protein structures and falsely reporting them as experimentally derived from X-ray diffraction experiments in nine (9) publications and in twelve (12) deposits in the PDB. ORI found that Respondent intentionally, knowingly, or recklessly falsified and/or fabricated the PDB coordinate files deposited for all of the eleven (11) structures (PDB entries 2HR0, 1BEF, 1RID, 1Y8E, 2A01, 1CMW, 1G40, 1G44, 2OU1, 1L6L, 2QID, and 1DF9) and the X-ray diffraction data (structure factors) corresponding to six (6) of the eleven (11) structures (PDB entries 2HR0, 1BEF, 1RID, 1Y8E, 2A01, and 1CMW).

with 2 C.F.R. § 180.845(c). On April 2, 2018, the HHS Debarring Official issued a final notice of debarment to begin on April 2, 2018, and end on April 1, 2028. Thus, the research misconduct findings set forth above became effective, and the following administrative actions have been implemented, beginning on April 2, 2018:

1. Dr. Murthy is debarred for a period of ten (10) years from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government, referred to as “covered transactions,” pursuant to HHS’ Implementation (2 C.F.R. Part 376) of Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (2 C.F.R. Part 180);
2. Dr. Murthy is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of ten (10) years; and
3. ORI will send a notice to the pertinent journals of the following publications that require retraction or correction and to the PDB for the following entries that require obsolescence, in accordance with 42 C.F.R. § 93.407(a)(1) and § 93.411(b):
 - □ Cell 104:301-311, 2001
 - □ Biochem. 41:11681-11691, 2002
 - □ Proc. Natl. Acad. Sci. USA 101:8924-8929, 2004
 - □ Biochem. 44:10757-10765, 2005
 - □ Proc. Natl. Acad. Sci. USA 103:2126-2131, 2006
 - □ PDB entries 1RID, 1Y8E, 2A01, 1G40, 1G44, 2OU1, and 1L6L

Research integrity is the adherence to ethical and professional standards throughout the research process, ensuring that the methodologies, data, and findings are trustworthy, transparent, and free from bias. Research integrity is a foundational principle that upholds the credibility of the scientific enterprise, ensuring that research not only meets high ethical and scientific standards but also serves the greater good of society.

Research integrity encompasses several key components:

1. Scientific Integrity: This involves employing rigorous and reliable methods to produce valid results.

Researchers must design studies appropriately, collect and analyze data accurately, and draw conclusions based on evidence, while being open to scrutiny and replication.

2. Professional Integrity: Researchers must uphold ethical principles, including honesty, accountability, and respect for intellectual property. This includes proper attribution of sources, avoiding conflicts of interest, and maintaining transparency in funding and affiliations.

3. Comprehensive Lifecycle Application: Research integrity applies to all stages of the research lifecycle, from the formulation of research questions and proposals to data collection, analysis, peer review, publication, and dissemination of findings. Each phase must be conducted with a commitment to ethical practices and accountability.

4. Impact on Society: Ensuring research integrity is vital for maintaining public trust in scientific inquiry, informing evidence-based public policy, and advancing knowledge. Reliable research contributes to societal progress, influences decision-making, and fosters innovation.

5. Commitment to Ethical Standards: Researchers are expected to follow established ethical guidelines, such as those provided by professional organizations and institutional review boards, ensuring the protection of human and animal subjects, as well as the responsible use of data.

To ensure research integrity, five fundamental principles must shape its conduct.

Embracing these principles allows researchers to maintain rigorous standards of integrity and make meaningful contributions to the advancement of knowledge and the betterment of society.



1. Honesty

Honesty involves presenting research goals, intentions, and findings truthfully and accurately.

Researchers are required to report on their methods and procedures transparently, ensuring that data collection is unbiased and free from manipulation. This principle also includes appropriately acknowledging the work of other researchers and providing valid interpretations based on the research findings.

2. Rigour

Rigour refers to strict adherence to established disciplinary norms and standards in conducting research. Researchers must follow agreed-upon protocols where applicable, ensuring consistency and reliability in data collection, analysis, and interpretation. Rigorous research practices are essential for producing robust and credible outcomes that withstand scrutiny.

3. Transparency and Open Communication

Transparency and open communication are vital for ensuring the credibility of research. Under this principle, researchers should disclose any potential conflicts of interest that could affect the research process or its results. They must accurately and comprehensively report the methods used for data collection, providing sufficient detail for others to replicate or verify the research. Additionally, researchers should make their findings widely available, including sharing negative or null results. Presenting work clearly and accessibly benefits both the academic community and the general public.

4. Accountability

The principle of accountability emphasizes the responsibilities of researchers, funders, and employers to ensure that everyone involved is held accountable for their actions and conduct. This principle also includes establishing appropriate measures to address allegations of research misconduct and unethical behavior, ensuring that violations are taken seriously and dealt with appropriately.

5. Respect for Participants

Respect for participants must be upheld at all stages of the research cycle. This includes showing regard for human participants, animals, the environment, and cultural artifacts. Researchers must prioritize the well-being, rights, and dignity of their participants throughout the research process. Ethical considerations, such as obtaining informed consent, are critical for safeguarding participants' protection. Additionally, researchers should ensure the integrity of research reports and records through accurate reporting.