“Medical Ethics, Respect for Persons and Conflicts of Interest”

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“It’s a wild, wild West out there in tissue land, with few sheriffs and a lot of shady characters meeting in the back rooms.”

Dr. Art Caplan, professor of bioethics at the University of Pennsylvania (Jablon 2004)
The Fraud Triangle

The fraud triangle is a model for explaining the factors that cause someone to commit occupational fraud. It consists of three components which, together, lead to fraudulent behavior:

1. Perceived unshareable financial need
2. Perceived opportunity
3. Rationalization

The second leg of the fraud triangle is perceived opportunity, which defines the method by which the crime can be committed. The person must see some way he can use (abuse) his position of trust to solve his financial problem with a low perceived risk of getting caught.

It is also critical that the fraud perpetrator be able to solve his problem in secret. Many people commit white-collar crimes to maintain their social status. For instance, they might steal to...
The **conundrum** for us is that there may be **research that puts the public at risk** but for oversight practitioners who care enough to conduct due diligence, it is extraordinarily difficult to do our work if the research projects are **unavailable for auditing**.

- **FOIA**: government’s records are the people’s business but (1) where to look, (2) inefficient processes, and (3) records sometimes withheld inappropriately.

- Now there are those who claim human subjects violations are few and far between. But are they right?

- We expect rigorous oversight and the preclusion of conflicts of interest in other fields, like the law, so why don’t we adopt the same standards when human lives are risk in research investigations and with field testing of new technologies?
The former chairman of UCLA’s orthopedic surgery department Robert Pedowitz reported concern that his colleague’s financial conflicts of interest could improperly impact patient care or research into new treatments (Terhune 2014b).

In a subsequent lawsuit about whistleblower retaliation, the University found that its faculty had engaged in no wrongdoing while offering Pedowitz a $10 million settlement (Terhune 2014b).

A Pro Publica study in 2014 noted that 41 board members from big pharmaceutical companies also held leadership positions at academic medical centers, with an average compensation of $312,564.

https://www.propublica.org/article/leaders-of-teaching-hospitals-have-close-ties-to-drug-companies-study-shows
The Bigger Picture

As reported, this comprises a set of cases which are widely reported on (e.g., we know them well) but the lessons we learn about the University of CA obviously have broader implications for research.

➢ From stealing the eggs of women for implantation into other women without consent at UCI (Yoshino 2006; Associated Press 2009)
➢ to the improper sale of cadavers at UCLA (Jablonski 2004)
➢ to organ donations to the wealthiest donors at UCLA (Glionna and Ornstein 2008)
➢ to killing patients by injecting live bacteria into their brains at UC Davis (Sacramento Bee 2013),
➢ to failing to disclose conflicts of interest (Terhune 2014a),

Medical school faculty at the University of California have for decades engaged in misconduct without sufficient oversight and little to no criminal prosecution.
Disclosures – Uniform Federal Policy

1. **Physician Payments Sunshine Act**
   - Mandates that drug manufacturers, as well as medical device and biologicals manufacturers, report payments and other valuable gifts to physicians and teaching hospitals (American Medical Association 2015). Manufactures must submit data annually on payments and other transfers of value made to covered recipients.

2. When medical school faculty **submit journal articles** or apply for grants, they are asked to disclose any financial relationships that might prove to be a conflict of interest.

3. All academic medical centers receiving **National Institutes of Health (NIH)** funding require annual disclosure of potential conflicts of interest; however, these disclosures are made internally and kept confidential (Pew 2013).
Disclosures – Local Policy

There is local variation in policy but let’s take a look at policy that has shaped the aforementioned cases.

UCLA Policy 150, the University’s policy on conflict of interest is that
“none of its faculty, staff, managers or officials shall engage in any activities which place them in a conflict of interest between their official activities and any other interest or obligation.”

When a financial conflict of interest emerges,
“Disclosures of financial interests are reviewed by the campus Conflict of Interest Review Committee (CIRC), appointed by the Chancellor and advisory to the Vice Chancellor for Research, or by other designated campus officials…recommendations are forwarded to the Vice Chancellor for Research who makes the final decision.”
People Underestimate the Effects of Conflicts of Interest

Research in the medical sciences supports that physicians are also **biased in their decision-making** when they have conflicts of interest:

One study that tracked how staff who “attended a grand rounds” sponsored by a drug company found that the **staff members were more likely to choose** that company’s treatment than their **non-attending colleagues**. However, many of the house staff did not recall what company sponsored the grand rounds.”

Dana and Lowenstein 2015: 253
Some people argue that field testing is excluded from informed consent. Whether that holds is a matter for debate, but we should keep in mind that no legal testing can violate US local, state and federal law.
FOR IMMEDIATE RELEASE
January 18, 2017

Final rule enhances protections for research participants, modernizes oversight system

Significant changes made in response to public comments

The U.S. Department of Health and Human Services and 15 other federal agencies today issued a final rule to update regulations that safeguard individuals who participate in research. Most provisions in the new rule will go into effect in 2018.

The new rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment.

The current regulations, which have been in place since 1991, are often referred to as the “Common Rule.” They were developed at a time when research was conducted predominantly at universities and medical institutions, and each study generally took place at a single site. Since then, research with human participants has grown in scale and become more diverse and data has become digital.

In September 2015, HHS and the other Common Rule agencies published a Notice of Proposed Rulemaking (NPRM), which drew more than 2,100 comments. In response to concerns raised during the extensive review process, the final rule contains a number of significant changes from the proposed rule, including the removal of a provision that would have required researchers to obtain consent before using a study participant’s non-identified biospecimens. The final rule maintains the current practice with respect to oversight of these specimens.
The Revised Common Rule (2017-2018)

“Most notably, the new rule does not adopt the proposal to cover researchers’ use of unidentified biospecimens (such as leftover portions of blood samples) and to require informed consent for such research. This proposal generated far more comments than any other, and by a substantial margin those comments opposed the proposal.”


What about victims of stalking, sexual assault and other harassment by medical providers? Do we revictimize them by using their data against consent?

Intelligence Surveillance Activities (NPRM at § .101(b)(1)(vi))

(1) NPRM Proposal
“The sixth category of excluded activities that will not be considered research involves surveys, interviews, surveillance activities and related analyses, or the collection and use of biospecimens where these activities are conducted by a defense, national security, or homeland security authority solely for authorized intelligence, homeland security, defense, or other national security purposes.”

“These activities may incorporate the collection and analysis of identifiable information, but they are not designed to develop or contribute to generalizable knowledge; rather, they are solely conducted to fulfill a department or agency's legal mandate to ensure the safety and protection of the United States, its people, and its national security interests. This exclusion codifies the current interpretation of the Common Rule.”
attention on higher risk studies, there is a new exemption for secondary research involving
identifiable private information if the research is regulated by and participants protected under the
HIPAA rules.

- Removal of the requirement to conduct continuing review of ongoing research studies in certain
instances where such review does little to protect subjects.

- Requirement that consent forms for certain federally funded clinical trials be posted on a public
website.

The final rule differs in important ways from the proposed rule. Some examples of proposals that,
based on feedback from the public, are not being adopted, include:

- The final rule does not adopt the proposal to require that research involving non-identified
biospecimens be subject to the Common Rule, and it does not require that consent be obtained in
order to conduct such research. In general, researchers can continue to use such biospecimens in
the way they are currently using them.

- To the extent that some of the NPRM proposals relied on tools or standards that had not yet been
proposed, the final rule either does not adopt those proposals or includes revisions to eliminate
such reliance. Examples of items that were not included in the final rule include a template to be
used for broad consent forms, and a decision tool to be used for making exemption determinations.

- The final rule does not expand the policy to cover clinical trials that are not federally funded.

- The final rule does not adopt the NPRM’s proposed concept of “excluded” activities. Generally,
activities proposed to be excluded are now described as not satisfying the definition of what
constitutes research under the regulations or are classified as exempt.

- The final rule does not include the proposed standardized privacy safeguards for identifiable private
information and identifiable biospecimens. Instead, in most respects, it retains the current approach
to privacy standards.

- The final rule does not adopt the proposal for more stringent criteria for obtaining a waiver of the
consent requirements for identifiable biospecimens.
New Technologies
**Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative (2013)**

*The BRAIN Initiative*

“Accelerate the development and application of new technologies that will enable researchers to produce dynamic pictures of the brain that show how individual brain cells and complex neural circuits interact at the speed of thought. These technologies will open new doors to explore how the brain records, processes, uses, stores, and retrieves vast quantities of information, and shed light on the complex links between brain function and behavior.”


Wolpe (2003) reported that one of the emerging issues in technology was that, “What would happen if we started using brain imaging routinely in the public sector...Imagine what that would mean for privacy...If you want to know if someone has a particular fetish, expose them to the fetish, and look at their functional MRI.”

*Emerging Technologies and Ethical Issues in Engineering* (National Academy of Engineering of the National Academies).
Do you see what I see? Researchers harness brain waves to reconstruct images of what we perceive

Dan Nemrodov (left) and Professor Adrian Nestor (left) have developed a technique that can harness brain waves gathered by data to show how our brains perceive images of faces (photo by Ken Jones)

Thursday, February 22 - 2018
Don Campbell
DARPA taps Lawrence Livermore to develop world's first neural device to restore memory

LIVERMORE, Calif. - The Department of Defense's Defense Advanced Research Projects Agency (DARPA) awarded Lawrence Livermore National Laboratory (LLNL) up to $2.5 million to develop an implantable neural device with the ability to record and stimulate neurons within the brain to help restore memory, DARPA officials announced this week.

The research builds on the understanding that memory is a process in which neurons in certain regions of the brain encode information, store it and retrieve it over time. It is not fully understood how these processes work, and memory loss occurs in many neurological conditions.

LLNL scientists hope to develop a device that can help restore memory by recording neural activity in one area of the brain and stimulating it in another. The device would be surgically implanted and placed in a specific location in the brain. It would be designed to record neural activity in one area of the brain and stimulate it in another.

LLNL scientists believe that the device could be used to help restore memory in people with memory loss due to neurological conditions such as Alzheimer's disease. They also believe that the device could be used to study the brain and how it works.

"We believe that this research has the potential to revolutionize the way we think about memory restoration," said LLNL scientist Dr. John Smith. "By developing a device that can help restore memory, we hope to gain a better understanding of how the brain works and how we can use this knowledge to help people with memory loss.

According to LLNL, the research is expected to take several years to complete. During this time, scientists will work to develop the device and test it in animals. They hope to begin testing the device in humans within the next five years.
Futuristic brain probe allows for wireless control of neurons

A study showed that scientists can wirelessly determine the path a mouse walks with a press of a button. Researchers at the Washington University School of Medicine, St. Louis, and University of Illinois, Urbana-Champaign, created a remote controlled, next-generation tissue implant that allows neuroscientists to inject drugs and shine lights on neurons deep inside the brains of mice. The revolutionary device is described online in the journal Cell. Its development was partially funded by the National Institutes of Health.

“It unplugs a world of possibilities for scientists to learn how brain circuits work in a more natural setting,” said Michael R. Bruchas, Ph.D., associate
Scientists at UC Berkeley have built a tiny, wireless sensor that might someday be able to monitor muscles or organs in real time, stimulate nerves to treat diseases, or allow people to control prosthetics with their minds.

The sensor is a 1-millimeter cube, about the size of a grain of sand. Researchers implanted them in the muscles and peripheral nerves of rats to record electrical activity, which provides information about how the nervous system is functioning in actual time. The research was published this month in Neuron.

One of the major problems in neurotechnology has been figuring out how to make durable and unobtrusive implants that can record and stimulate nerves. There are electrodes that connect a human brain to a prosthetic, such as a robotic arm, but they are cumbersome and have not been engineered to last for decades.
If the brain initiative involves massive movement of monies with many universities and contractors as primary actors, what research abuses have we detected so far?

➢ The revered fraud triangle applied suggests that there is substantial opportunity for misconduct.
➢ General silence in media...why not reports of abuse?

More broadly, the challenges faced by oversight underscore new legal questions as well

➢ What does “being in custody” mean with new technology? (under police control, interrogation)
➢ Theoretically, a suspect could be in custody indefinitely, even though it would be very difficult to prove with new technologies.

Also challenges traditional models for cruel and unusual punishment (duration, hours etc).

➢ Chicago’s Police Commander Jon Burge is widely reported for running a decades-long torture ring where he hooked suspects to an electronic torture box and shocked them until they made false confessions.
➢ How to detect these abuses as technologies shrink and become wireless?

Recommendations

➢ Recommendation #1 Introduce Regulations that Researchers and Oversight Officials Recuse Themselves from Projects with Human Subjects where They Have a Financial Conflict of Interest

➢ Recommendation #1 Subpart A. Make Sure Oversight Officials Do Not Have Conflicts of Interest Themselves

➢ Recommendation #1 Subpart B. Make sure that Deliberations about Conflicts of Interest Make Central Respect for Persons and the Informed Consent of Human Subjects

➢ Recommendation #2 Mandate Common Rule Compliance and Vulnerable Population Protections for All Public and Private Institutions Engaging in Research with Human Subjects

➢ Recommendation #2 Subpart A. Mandate that Courts Formally Declare Someone as Mentally Incapacitated With Due Process (A Hearing Where the Human Subject Has a Right to Be Present) Before Researchers Can Enroll Such an Individual without Informed Consent

➢ Recommendation #2 Subpart B Produce a Comprehensive Database for Research with Human Subjects where There is Greater than Minimal Risk