What is investigative journalism?

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Some definitions

- [A] form of journalism in which reporters deeply investigate a single topic of interest, such as serious crimes, political corruption, or corporate wrongdoing.

  Wikipedia

- [T]here is broad agreement of its major components: systematic, in-depth, and original research and reporting, often involving the unearthing of secrets. Others note that its practice often involves heavy use of public records and data, with a focus on social justice and accountability

  Global Investigative Journalism Network

- "Investigative journalism involves exposing to the public matters that are concealed – either deliberately by someone in a position of power, or accidentally, behind a chaotic mass of facts and circumstances that obscure understanding. It requires using both secret and open sources and documents."

  Story-Based Inquiry: A manual for investigative journalists

Some basic principles

- The public good, social justice
- Holding those in power accountable
- Original research
- Revealing, exposing
- Giving voice to the voiceless
- More watchdog than explainer

How is the work actually done?

- Leaks, whistleblowers
- Documents
- Data
- Background research
- Cultivating sources
- Protecting confidential sources

So much to do, so little time ....

From the Wikipedia entry:

An investigative journalist may spend months or years researching and preparing a report.

You have less than ten weeks!

Don’t panic!

- Leaks, whistleblowers
- Documents
- Data
- Background research
- Cultivating sources
- Protecting confidential sources

These can all become part of your regular reporting toolkit. Don’t keep them in reserve for major projects.

But you need a plan!

And one that can be executed in a matter of weeks.

How do I start?

You may need to spend some initial time getting up to speed with the background:

- Speak to informed sources.
- Do some initial exploration of documents, data.

But you *quickly* need:

Questions, questions, questions ...

... with a clear and deliverable plan of how you your reporting will find answers.

Think story, not topic!

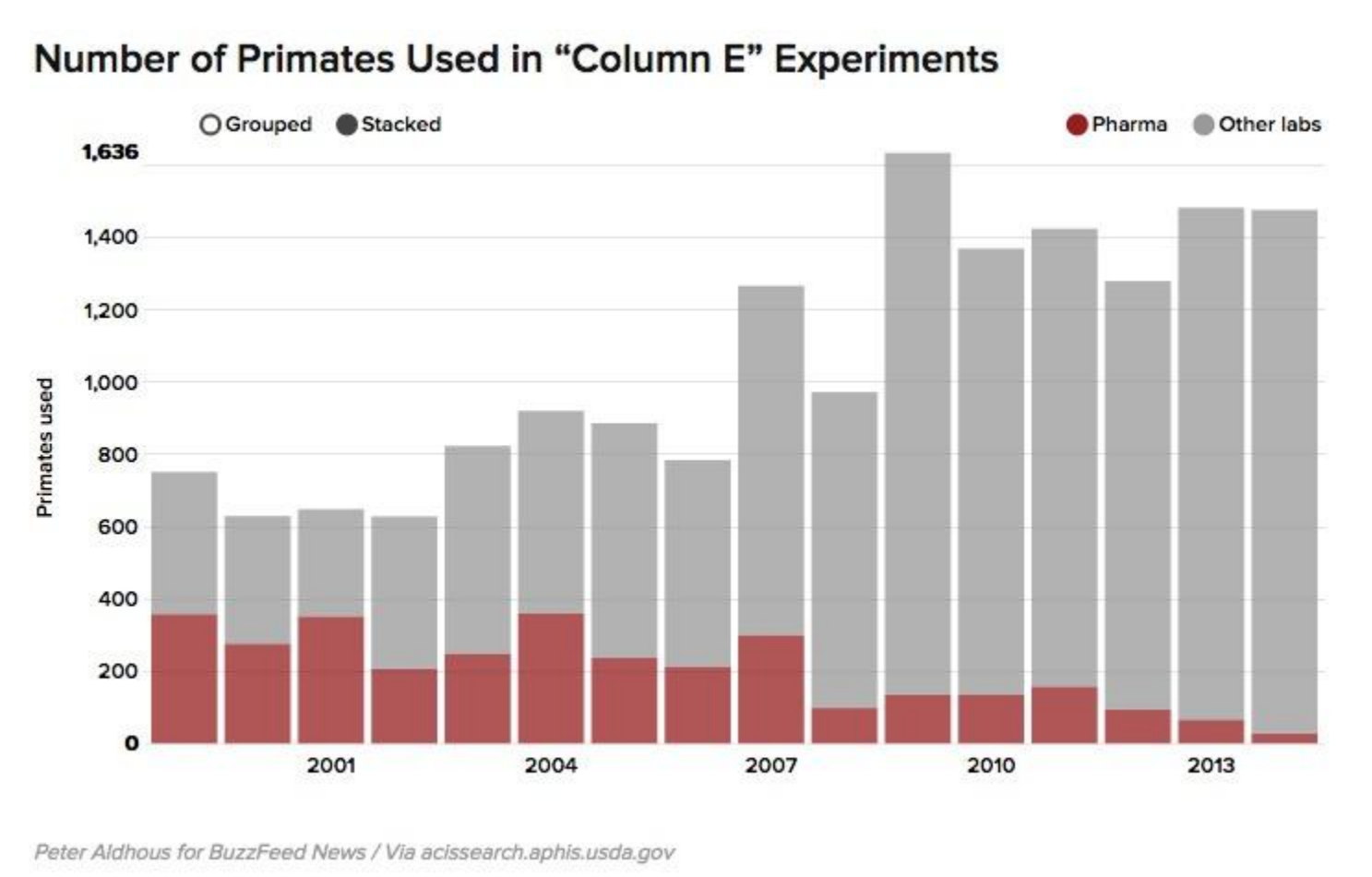
You should be working toward potential heds and deks, depending on the answers to your questions.

The Silent Monkey Victims Of The War On Terror

Thousands of animals have been exposed to deadly pathogens, chemicals, and radiation so that scientists can develop medicines to protect Americans from weapons of mass destruction. Was all this suffering really necessary?

How did that story start?

I knew I wanted to explore the ethical debate around primates in biomedical research. That was a topic. It became a story, driven by specific questions, when I made a preliminary version of this chart:



Which labs?

Institutions That Perform "Column E" Primate Experiments

Search:

Year	Name	Primates Used
2014	Lovelace Respiratory Research Institute	431
2014	Battelle Memorial Institute	270
2014	USAMRIID	249
2014	Texas Biomedical Research Institute	98
2014	National Institutes of Health	70
2014	Armed Forces Radiobiology Research Institute	56
2014	University of Maryland, Baltimore	47
2014	University of Texas, Galveston	45
2014	SRI International	44
2014	University of Pittsburgh	37

Scroll table to see more / Peter Aldhous for BuzzFeed News / Via acissearch.aphis.usda.gov

Why is this happening?

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

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Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Emergency Preparedness and Response

Home > Emergency Preparedness and Response > Counterterrorism and Emerging Threats > Medical Countermeasures Initiative > MCM Regulatory Science

MCM Regulatory Science

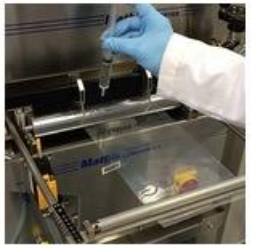
- **Animal Rule Information**
- Extramural Research
- Intramural Research
- MCMi Collaborations
- MCMi Regulatory Science Presentations

Resources for You

- What are Medical Countermeasures?
- 2014 MCMi Regulatory Science Symposium - Webcast Recordings [ARCHIVED]
- Counterterrorism-Related Legislation
- MCMi News and Events
- About MCMi

Animal Rule Information

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT



Before a medical product can be approved by FDA, the sponsor must prove efficacy—that the product works. In some cases, such as developing medical countermeasures for potential bioterror threats, human challenge studies (exposing people to the threat agent) would not be ethical or feasible.

In these cases, FDA may grant approval based on well-controlled animal studies, when the results of those studies establish that the drug or biologic product is reasonably likely to produce clinical benefit in humans. The product sponsor must still demonstrate the product's safety in humans.

Final Guidance for Industry: Product Development Under the Animal Rule (PDF, 574 KB)

August 2016: FDA is **proposing to amend the regulations for good laboratory practice** (GLP) for nonclinical laboratory studies to require a complete quality system approach, referred to as a GLP Quality System, when safety and toxicity studies support or are intended to support applications or submissions for products regulated by FDA. As part of proposed changes to this rule, FDA seeks **comment on the impact of expanding part 58** to include covered Animal Rule studies, and what other changes to the regulations, beyond amending the scope and definitions, are needed to address issues unique to covered Animal Rule studies. Comment by **November 22, 2016**.

The initial pitch

Starting to dig into the USDA's animal care database, I've come across what I think is an interesting story: a marked increase in recent years in the number of primates being subjected to experiments involving pain and distress, without any alleviation of that suffering with painkillers, tranquilisers etc. I need to dig further, but it looks like this has been driven by biodefense research, in particular Project Bioshield's efforts to develop new drugs to combat acute radiation syndrome, anthrax etc.

Institutions have to file a document explaining why they're doing experiments that cause suffering that's not alleviated, and the latest documents for Lovelace and Battelle (attached) indicate that the primate experiments are for biodefense work. Some of this is pretty nasty stuff: lethal irradiation and infection with highly pathogenic infectious agents.

Specifically to allow development of new countermeasures against biological and radiological weapons, the FDA in 2002 introduced the "Animal Rule," which allows testing in animals instead of human clinical trials if the latter are not ethically feasible. So if my interpretation holds up with further reporting, this has been brewing for a while. However, I don't think what it means in terms of primate welfare has been much debated. I'd also like to explore whether these experiments, without alleviation of suffering, absolutely *have* to be run, or whether there are alternatives.

Which experiments?

Study 2: (37) Non-Human Primate *(African Green)*

Exposure to a multiple LD50 dosage of the infectious agent results in fever approximately 48 – 84 hours post-exposure. Generally little other evidence of pain or distress is noted at that time. If untreated, pain and distress will manifest initially as inappetence and dehydration resulting in changes in feces/urine output/consistency. As disease progresses increases in respiration and heart rate, weight loss, reduced grooming, cough, changes in posture, lethargy and nasal and ocular discharge are noted. Prior to moribundity persistent tachycardia, weakness, bloody cough, drop in temperature, diaphragmatic breathing, seizure, non-responsiveness may be noted. The giving of pain or stress relieving agents is contraindicated because it may interfere in determining the efficacy of the therapeutic. Furthermore, we need to study the natural progression of the disease process in the absence and presence of the therapeutic agent without the confounding influence of another agent on the pathophysiological process of animal infection. It is likely the use of analgesics will interfere with the accurate measurements of the disease process or with the antibiotic treatment whose efficacy is being assessed. Narcotic analgesics were shown to interfere with the mechanism(s) responsible for interferon production (Geher, W.F. et al., J. Toxicol Environ Health 2:577-582, 1977; Hung, C. Y. et. al. Proc Soc Exp Biol Med 142:106-111-1973). Moreover opioids can suppress Natural Killer (NK) cell activity (Beilin, B., et al., Brain Behav Immun 3: 129-137, 1989). Also, analgesics including buprenorphine can cause histamine release (Marone, G., et al Int Arch Allergy Immunol 124:249-252, 2001; Stellato, C., and Marone, G., Chem Immunol 62: 108-131, 1995) and respiratory depression (Soma, L.R., Ann NY Acad Sci 406: 32-47, 1995). Histamine is a well-known inflammatory mediator and plays a central role in the pathogenesis of allergic and inflammatory diseases by modulating vascular and airway responses. lipopolysaccharide (LPS).

Which experiments?

Levofloxacin Cures Experimental Pneumonic Plague in African Green Monkeys

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Abstract

Background: *Yersinia pestis*, the agent of plague, is considered a potential bioweapon due to rapid lethality when delivered as an aerosol. Levofloxacin was tested for primary pneumonic plague treatment in a nonhuman primate model mimicking human disease.

Methods and Results: Twenty-four African Green monkeys (AGMs, *Chlorocebus aethiops*) were challenged via head-only aerosol inhalation with 3–145 (mean = 65) 50% lethal (LD_{50}) doses of *Y. pestis* strain CO92. Telemetered body temperature >39°C initiated intravenous infusions to seven 5% dextrose controls or 17 levofloxacin treated animals. Levofloxacin was administered as a "humanized" dose regimen of alternating 8 mg/kg and 2 mg/kg 30-min infusions every 24-h, continuing until animal death or 20 total infusions, followed by 14 days of observation. Fever appeared at 53–165 h and radiographs found multilobar pneumonia in all exposed animals. All control animals died of severe pneumonic plague within five days of aerosol exposure. All 16 animals infused with levofloxacin for 10 days survived. Levofloxacin treatment abolished bacteremia within 24 h in animals with confirmed pre-infusion bacteremia, and reduced tachypnea and leukocytosis but not fever during the first 2 days of infusions.

Conclusion: Levofloxacin cures established pneumonic plague when treatment is initiated after the onset of fever in the lethal aerosol-challenged AGM nonhuman primate model, and can be considered for treatment of other forms of plague. Levofloxacin may also be considered for primary presumptive-use, multi-agent antibiotic in bioterrorism events prior to identification of the pathogen.

Citation: Layton RC, Mega W, McDonald JD, Brasel TL, Barr EB, et al. (2011) Levofloxacin Cures Experimental Pneumonic Plague in African Green Monkeys. PLoS Negl Trop Dis 5(2): e959. doi:10.1371/journal.pntd.0000959

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Is there a controversy about this?

From a National Academy of Sciences report:

models. Details of supportive care should be discussed with the FDA early in the planning stages before studies are initiated. As a reasonable measure to incorporate in the study design, it is not only a more humane approach but may allow fewer animals to be used in accordance with the Three Rs. Experience from such experimental protocols may be helpful in the event of countermeasure trials against an "unknown-unknown." The Committee recognizes that the nature of biocontainment imposes difficulties in the implementation of the above. **Therefore, the Committee recommends that the TMT define the basic principles of such an approach, including guidelines for the care and use of animals in research in biocontainment facilities.**

Finally, the Committee concludes that the potential advances in knowledge and benefits to the warfighters should be weighed against the duration and severity of animal pain and distress. Further, the Committee believes that the application of refinement strategies and reduction approaches (as discussed in Chapter 5) could improve laboratory animal welfare and safeguard the quality of biodefense research. Moreover, the recommended comprehensive strategy of implementing the Three Rs, incorporating compartmentalization, and enhancing collection and analysis of human data reduces the dependency of this field of research on nonhuman primates by maximizing the value of data derived from all research. **The Committee recommends that, where possible, the TMT should encourage efforts to replace nonhuman primates as the animal of choice in biodefense research.** Such efforts coupled with unhindered access to data and publishing of all results—including negative ones—are critical steps to ensure that this data are beneficial, animals are used judiciously, and unnecessary duplication of work is avoided.

My reporting plan

Analysis of USDA to look at numbers of primates used in “Column E” experiments, involving unalleviated pain and suffering. Surprisingly, numbers had risen. Initial research revealed that this was driven by biodefense research, and the FDA’s “Animal Rule.” At this point, I knew the questions to drive my reporting, and I had heds/deks in mind.

- Use documents submitted to USDA, scientific literature searched at PubMed, and approvals under the Animal Rule to identify experiments involved.
- Speak to specialists in infectious disease, radiation medicine, and animal welfare to ask:
    - Did these experiments need to be run on monkeys?
    - Did so many animals need to be used?
    - Did the experiments need to involve unalleviated pain/suffering?
- Seek comments/interviews from labs involved, the federal agencies backing the research, and the FDA.

Define the minimum deliverable story …

(but aim higher)

The *inside* track

Members of the US National Academy of Sciences have long enjoyed a privileged path to publication in the body's prominent house journal. ***Meet the scientists who use it most heavily.***

BY PETER ALDHOUS

In April, the US National Academy of Sciences elected 105 new members to its ranks. Academy membership is one the most prestigious honours for a scientist, and it comes with a tangible perk: members can submit up to four papers per year to the body's high-profile journal, the venerable *Proceedings of the National Academy of Sciences* (*PNAS*), through the 'contributed' publication track. This unusual process allows authors to choose who will review their paper and how to respond to those reviewers' comments.

For many academy members, this privileged path is central to the appeal of *PNAS*. But to some scientists, it gives the journal the appearance of an old boys' club. "Sound anachronistic? It is," wrote biochemist Steve Caplan of the University of Nebraska, Omaha, in a 2011 blog post that suggested the contributed track could be used as a "dumping ground" for certain papers. Editors at *PNAS* have strived to dispel that perception.

With *PNAS* currently celebrating its centenary, the news team at *Nature* decided to examine the contributed track, both to assess its scientific impact and to see which members use it most heavily and why. After analysing a decade's worth of *PNAS* papers, we found that only a small number of scientists have used the track at close to the maximum allowable rate. The group includes some of the biggest names in science, and six of them sit on the editorial board at the journal. These scientists say the main motivator for using the contributed track is an intense frustration with the peer-review process at other high-profile journals, which they argue has become excessive and laborious.

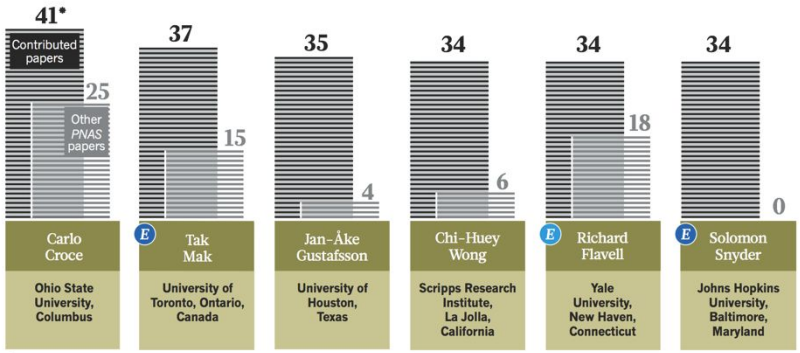
Our analysis also suggests that the efforts by *PNAS* to prevent abuse of the contributed track and to boost the quality of papers published by this route are bearing fruit. Although contributed *PNAS* papers attract fewer citations than those handled through the journal's standard review process, the gap has narrowed in recent years. "We have worked really hard at this," says Alan Fersht, a biophysicist at the University of Cambridge, UK, one of *PNAS*'s associate editors and a heavy user of the contributed track.

A PRIVILEGE TO PUBLISH

An inside track to publication for academy members rests deep in *PNAS*'s DNA. The journal was established in 1914 with the explicit goal of publishing members' "more important contributions to research" in addition to "work that appears to a member to be of particular importance". That remit led to the creation of two publishing tracks: contributed and 'communicated' papers -- manuscripts sent by non-members to colleagues in the academy, who shepherded them through review.

Who are the power users?

Just 13 members of the US National Academy of Sciences consistently published three or more papers per year in the 'contributed track' at *PNAS* during the past decade. 'Other' papers include direct submissions, reviewed in the normal way, and papers contributed or communicated by other members.



The initial pitch

Any interest from *Nature* in exploring how members of the National Academy use the publishing perk that comes along with membership: The ability to submit up to four papers a year to *PNAS*, choosing their own reviewers and directing the process of peer review?

I'm proposing a systematic survey of probably 10 years of papers in *PNAS* (2004-2013), looking at how academy members have used the contributed track (and also direct submissions). I doubt *PNAS* will give me the data, but it should be relatively easy to write a script to webscrape it. I'll then look at how the use of the various tracks distributes across the academy's 2000+ living members (data from here).

What I expect we'll find is a very skewed distribution with a long, long tail of academy members who barely or never use the perk, and a relatively small number of individuals who use it relatively frequently. I suspect *Nature*'s readers would be really interested in reading an article that identifies these individuals and speaks to them about their decision to send so many of their papers down this route.

The initial pitch

I should be able to slice the results by their subject areas, pull in citation data for all of the papers from the Web of Science … and look at the impact of the papers.

Although citations are not the only way to judge the impact of papers, they are the most readily available and widely researched measure. We repeated and extended Rand and Pfeiffer's analysis, considering papers published from 2004 to 2011. Overall, the conclusion was the same: the difference between citation rates for directly submitted and contributed papers was not large — controlling for other factors such as discipline, contributed papers garnered about 4.5% fewer citations — but it was statistically significant. *Nature*'s analysis also suggests that the gap in citation rates between directly submitted and contributed papers has been narrowing, and this does not seem to be because more-recent papers have yet to acquire enough citations for the difference to show.

Managing your work

- Include deadlines for the completion of each part of your reporting plan.
- Regularly review progress against your plan, and adjust as necessary
- Include Stop/Go checkpoints. You need to recognize when a story isn't panning out. If it isn't you must change direction.
- Run pilot analyses/document work/other reporting to confirm that there is a story before embarking on a large amount of work that may or may not yield results.

The real key to success

- Email, email, email!
- Phone, phone, phone!

It’s the intensitivity of reporting effort that separates successful reporters from the also-rans.

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