

Human Guinea Pigs

Ever considered smoking pot for a living? Or having your veins shot full of red dye? Or testing new medications that might kill you? Join the growing ranks of Boston's "professional patients."

WILD-EYED AND DISHEVELED, his mustard-colored T-shirt ruffled and blond curls dancing about his head, Jeffrey Conolly bursts into Dali restaurant half an hour late, shouting apologies across the crowded room. "I was puttin' out fires, puttin' out fires," he says, breathing heavily. Before he's whipped off his corduroy jacket and plopped into a chair, he's demanding a pitcher of amber ale.

"Right now!" he barks, his flailing arms just missing the waiter's startled face. A mug of

beer appears, along with regrets for the lack of ale or pitchers. "Then keep this glass full at all times, understand?" snaps Conolly, who proceeds to drink steadily for the next hour.

His urgency—in fact, the request itself—is surprising, since Conolly is supposed to be cutting back on his drinking. Every day for the past four months, as a volunteer in the study of a new anti-drinking drug, he's swallowed a series of eight color-coded pills. "It's not Antabuse. You don't vomit when you drink," he says. "But it's supposed to be a tool, and you have to use some willpower, which

I'm not doing too much of," he admits, knocking back another mouthful.

Maybe Conolly is in the control group, those who are given placebos instead of the actual drug. Since it's a double-blind study, neither he nor the researchers know what he's taking. But he's losing weight rapidly, so he's sure he got the good stuff.

"I've dropped 50 pounds," says Conolly, 46, patting his still-ample belly. This side effect pleases him. For more than two decades, Conolly, the manic force behind one of Boston's seminal garage bands, the Lyres, has been a celebrity on the local music scene. "I'm supposed to be a thin guy in black jeans, but ever since my wife left me and I OD'ed on drugs and stuff, I started using food as a drug." Drinking more, too. When his current girlfriend spotted an ad seeking volunteers for a clinical study of a new anti-drinking drug, he agreed to sign up. Volunteers would get paid, of course—between \$500 and \$1,000.

Doesn't he worry about introducing an untested chemical into his body? Conolly pauses, looking puzzled. To a guy who started drinking when he was 11 (he started smoking pot soon after) and has OD'ed five times, it's a dumb question. In Boston's underground music world, volunteering for scientific research may rank among the least risky things to do. It's also easy money for people strapped for cash, and it gives you bragging rights, too—as in, What's the weirdest thing you've ever gotten paid to do?

Conolly participated in his first medical experiment about 20 years ago. Since then, he has served as a human guinea pig somewhere "between 10 and 20 times" at a variety of Boston hospitals and universities. He's been burned with ultraviolet light in a cancer study and injected with red dye. ("That was a 9 on the ridiculous meter. Like, *What stupid human trick can I do to make 50 bucks?*") Then there was a two-month fat-protein study at Tufts, where he earned \$2,000 for getting injections every day. "Extremely gratifying," he says. "Fat wads of cash."

Call him a guinea pig. A medical prostitute. A "professional participant," as they say at CenterWatch, a Boston company that publishes a Web site (www.centerwatch.com)



WEIRD SCIENCE: At any given time, about 50,000 people take part in clinical trials in Boston.

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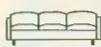
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and books for researchers and volunteers in clinical studies. Conolly is part of a little-noticed local subculture of professional guinea pigs. He doesn't care what you call him or do to him—as long as you pay him.

WITH ITS SCORES OF HOSPITALS, universities, and biotech companies, Boston has an inexhaustible demand for clinical-study subjects. They are needed to test cutting-edge medicines, to undergo diet studies, to stay awake for days on end, even to ingest high-grade street drugs. "The joke around here is that the next big bottleneck in Boston isn't the Big Dig, but patient recruitment," says Dr. John Yee of BBK Healthcare, a Newton company that finds human volunteers for clinical trials nationwide.

Somewhere around 50,000 people in the Boston area take part at any given time in trials for new drugs, medical devices, and procedures. The demand

There's never a shortage of volunteers to participate in medical studies of male baldness or sexual dysfunction.

for subjects is expected to increase with the influx of such companies as Novartis AG, the Swiss pharmaceutical giant that is opening an office in Cambridge. Of the total pool of subjects, 3 percent—or 1,200 to 1,500 people—are professional participants who segue from one experiment to the next, estimates Kenneth Getz, president and CEO of CenterWatch.

"These are people who maybe can earn \$10,000 to \$12,000 a year by participating in clinical trials," Getz says. Like Conolly, "they might be musicians or people who live flexible lives and are looking for bragging rights and a way to make money." It's no surprise that a community of "professionals" has crystallized, considering that institutions and the federal government hand out more than \$4 billion nationwide in research grants to test subjects every year. There's even a national Web site for them, www.guineapigzero.com.

Private companies and academic institutions pay people like Conolly because they're essential to scientific research. Typically, it takes 6,000 human subjects to test the safety and effectiveness of a single new drug, and Yee says finding them is

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one of the biggest hurdles in the business. (There's never a shortage of volunteers for studies of male baldness or sexual dysfunction.) That's why it's impossible to miss those ubiquitous flyers posted in Central and Davis squares, on college campuses and the T, and in newspaper, TV, and Internet ads, all offering money or free physical exams. Volunteers range from bored college kids to dying patients hoping for a last-ditch miracle cure.

No one disagrees that human-subject research saves millions of lives in the long run. But ethicists worry that some volunteers, whether drawn by money or altruism (60 percent claim their motivation is to advance science, Getz says), take it too casually.

"The people who make a career of these [experiments] are normal, healthy volunteers. And normal, healthy volunteer subjects have died," says Susan Fish, director of the Institutional Review Board at Boston University Medical Center, which oversees human research there. Such deaths are rare, but in 2001, a healthy 24-year-old woman named Ellen Roche died during an asthma study at Johns Hopkins University.

"There is probably almost no research that is absent of risk," says Fish. "One of the things the volunteers must consider is not

only how much money they're going to make and how much good they'll do for society, but also the risk."

CHRISTINE (NOT HER REAL NAME), A NEWCOMER to Cambridge in her mid 40s, was focused only on money when she answered an ad last year seeking people in "troubled relationships." Unemployed, she saw no danger in giving a few hours of her time to participate in a study at Brigham and

Amanda spotted an advertisement in the *Phoenix* that offered \$500 for a study at McLean Hospital. Her job? To smoke pot.

Women's Hospital, especially since she'd had a positive experience in a study of anxiety and eating disorders at Harvard. She talked her boyfriend into signing up (they each made \$150), and Brigham researchers had them sign paperwork that described the protocol. But Christine raced through it and didn't realize what was about to happen.

First she and her boyfriend were interviewed separately and asked to describe the

three worst points of conflict in their relationship. Then they were reunited to listen to the taped responses, and given three minutes to respond to each point. Within minutes, they were in the middle of a horrible argument—which was videotaped. After they were separated again to watch the videotape of their argument, Christine burst from the room in tears, "totally traumatized."

"If I knew he was going to hear [my answers], I definitely would have answered differently," she says. "I don't think they explained it well enough. It might have been in all those sheets of paper, but there was so much reading material." Although the researchers had her speak immediately with a therapist, Christine spent the next month in a "deep depression," she says.

Some researchers are so busy with the cumbersome paperwork that they don't focus on whether volunteers really understand what they're getting into, says Dr. Greg Koski, who left his post in November as the first director of the two-year-old federal Office for Human Research Protections to return to Massachusetts General Hospital and his Harvard teaching position.

CenterWatch's Kenneth Getz agrees. "Informed consent is a misnomer," he says.



Do not go where
the path may lead,
go instead where
there is no path
and leave a trail.

Ralph Waldo Emerson

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"Basically, what the patient is doing is giving their consent that they've read a form. They're not informed, and they don't understand the process."

This issue of consent is central to a national reform movement spurred by the highly publicized death in 1999 of 18-year-old Jesse Gelsinger, who wasn't adequately warned of potential risks in an experimental gene therapy at the University of Pennsylvania, according to a lawsuit filed by his family. ("It was the fastest settlement I've ever seen in my life, probably for good reason," says Wendy Mariner, a professor of health law at BU's School of Public Health.)

Massachusetts is at the forefront of the effort toward greater protection: Senator Edward Kennedy, a primary architect of initial human-subject regulations in the '70s, has filed legislation to provide greater protections. In the private sector, BBK Healthcare launched a "good recruitment practice" initiative last summer to encourage ethical standards for recruiting patients, while CenterWatch has published *Informed Consent: The Consumer's Guide to Volunteering for Clinical Trials*. This emphasis on patient safety is critical, says Koski, who himself has volunteered in a hepatitis vaccine study,

"because, otherwise, the public isn't going to volunteer, and if they don't volunteer, there isn't going to be any research."

Another concern is the amount of money paid to volunteers: When does it become coercive? Since so many volunteers are students or otherwise financially vulnerable, including a growing number of people in developing countries, the medical community must ensure they're not exploited.

"We shouldn't be paying them to do things they wouldn't otherwise do," says Koski. "It's also important to make sure the research is scientifically meritorious and safe. It's one thing to pay them to do something that's already been reviewed. That's very different from saying, 'Hey, why don't you jump off the side of a building?' and seeing how they survive."

THERE WAS NO ISSUE OF COERCION for Amanda (also not her real name). Ten years ago, she was a senior at BU doing work-study jobs for \$6 an hour when she spotted an ad in the *Boston Phoenix* that offered \$500 for a study at McLean Hospital. Amanda's job? To smoke pot. Really good pot, to be specific.

"The nurse said, 'Okay, I'm going to give

you a cigarette. I don't know if it's placebo or not.' It looked like a Marlboro," says Amanda. "She would say, 'Put it up to your lips, inhale 1, 2, 3, hold 1, 2, 3, exhale 1, 2, 3.' I thought, 'That's not how you toke at a party.'"

Amanda got very stoned very fast and couldn't finish the cigarette. "What do you think? Is it real?" the nurse asked.

"Oh, yes, it's definitely strong," Amanda answered. "It's no dirt weed like you get at BU parties."

In a subsequent test of her balance, Amanda fell headfirst off a platform into a padded wall. Before sending her home in a taxi, the nurse fetched her a meal. ("Best hospital food I've ever had.") "I got \$500 for getting high, transportation included, and snacks," Amanda says.

Not a bad day's work. The point? To find out what pot does to motor skills, as if its effects were ever in question.

As for human guinea pig Jeffrey Conolly, he still has a couple of months to go in the alcohol study, but he's delighted with the unexpected weight loss. He's hoping FDA approval comes fast. "I like that anti-drinking drug so much," he says, "that when I see my primary-care physician, I'm gonna request he get me a prescription." **B**

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