My IRB Nightmare

Posted on August 29, 2017 by Scott Alexander

Epistemic status: *Pieced together from memory years after the event. I may have mis-remembered some things or gotten them in the wrong order. Aside from that – and the obvious jokes – this is all true. I'm being deliberately vague in places because I don't want to condemn anything specific without being able to prove anything.*

September 2014

There's a screening test for bipolar disorder. You ask patients a bunch of things like "Do you ever feel really happy, then really sad?". If they say 'yes' to enough of these questions, you start to worry.

Some psychiatrists love this test. I hate it. Patients will say "Yes, that absolutely describes me!" and someone will diagnose them with bipolar disorder. Then if you ask what they meant, they'd say something like "Once my local football team made it to the Super Bowl and I was really happy, but then they lost and I was really sad." I don't even want to tell you how many people get diagnosed bipolar because of stuff like this.

There was a study that supposedly proved this test worked. But parts of it confused me, and it was done on a totally different population that didn't generalize to hospital inpatients. Also, it said in big letters THIS IS JUST A SCREENING TEST IT IS NOT INTENDED FOR DIAGNOSIS, and everyone was using it for diagnosis.

So I complained to some sympathetic doctors and professors, and they asked "Why not do a study?"

Why *not* do a study? Why not join the great tradition of scientists, going back to Galileo and Newton, and make my mark on the world? Why not replace my griping about bipolar screening with an experiment about bipolar screening, an experiment done to the highest standards of the empirical tradition, one that would throw the entire weight of the scientific establishment behind my complaint? I'd been writing about science for so long, even doing my own informal experiments, why not move on to join the big leagues?

For (it would turn out) a whole host of excellent reasons that I was about to learn.

A spring in my step, I journeyed to my hospital's Research Department, hidden in a corner office just outside the orthopaedic ward. It was locked, as always. After enough knocking, a lady finally opened the door and motioned for me to sit down at a paperwork-filled desk.

"I want to do a study," I said.

She looked skeptical. “Have you done the Pre-Study Training?”

I had to admit I hadn’t, so off I went. The training was several hours of videos about how the Nazis had done unethical human experiments. Then after World War II, everybody met up and decided to only do ethical human experiments from then on. And the most important part of being ethical was to have all experiments monitored by an Institutional Review Board (IRB) made of important people who could check whether experiments were ethical or not. I dutifully parroted all this back on the post-test (“Blindly trusting authority to make our ethical decisions for us is the *best* way to separate ourselves from the Nazis!”) and received my Study Investigator Certification.

I went back to the corner office, Study Investigator Certification in hand.

“I want to do a study,” I said.

The lady still looked skeptical. “Do you have a Principal Investigator?”

Mere resident doctors weren’t allowed to do studies on their own. They would probably screw up and start building concentration camps or something. They needed an attending (high-ranking doctor) to sign on as Principal Investigator before the IRB would deign to hear their case.

I knew exactly how to handle this: one by one, I sought out the laziest attendings in the hospital and asked “Hey, would you like to have your name on a study as Principal Investigator for free while I do all the actual work?” Yet one by one, all of the doctors refused, as if I was offering them some kind of plague basket full of vermin. It was the weirdest thing.

Finally, there was only one doctor left – Dr. W, the hardest-working attending I knew, the one who out of some weird masochistic impulse took on every single project anyone asked of him and micromanaged it to perfection, the one who every psychiatrist in the whole hospital (including himself) had diagnosed with obsessive-compulsive personality disorder.

“Sure Scott,” he told me. “I’d be happy to serve as your Principal Investigator”.

A feeling of dread in my stomach, I walked back to the tiny corner office.

“I want to do a study,” I said.

The lady still looked skeptical. “Have you completed the New Study Application?” She gestured to one of the stacks of paperwork filling the room.

It started with a section on my research question. Next was a section on my proposed methodology. A section on possible safety risks. A section on recruitment. A section on consent. A section

on… wow. Surely this can't *all* be the New Study Application? Maybe I accidentally picked up the Found A New Hospital Application?

I asked the lady who worked in the tiny corner office whether, since I was just going to be asking bipolar people whether they ever felt happy and then sad, maybe I could get the short version of the New Study Application?

She told me that *was* the short version.

"But it's twenty-two pages!"

"You haven't done any studies before, have you?"

Rather than confess my naivete, I started filling out the twenty-two pages of paperwork. It started by asking about our study design, which was simple: by happy coincidence, I was assigned to Dr. W's inpatient team for the next three months. When we got patients, I would give them the bipolar screening exam and record the results. Then Dr. W. would conduct a full clinical interview and formally assess them. We'd compare notes and see how often the screening test results matched Dr. W's expert diagnosis. We usually got about twenty new patients a week; if half of them were willing and able to join our study, we should be able to gather about a hundred data points over the next three months. It was going to be easy-peasy.

That was the first ten pages or so of the Application. The rest was increasingly bizarre questions such as “Will any organs be removed from participants during this study?” (Look, I promise, I’m not a Nazi.)

And: “Will prisoners be used in the study?” (COME ON, I ALREADY SAID I WASN’T A NAZI.)

And: “What will you do if a participant dies during this research?” (If somebody dies while I’m asking them whether they sometimes feel happy and then sad, I really can’t even promise so much as “not freaking out”, let alone any sort of dignified research procedure).

And more questions, all along the same lines. I double-dog swore to give everybody really, really good consent forms. I tried my best to write a list of the risks participants were taking upon themselves (mostly getting paper cuts on the consent forms). I argued that these compared favorably to the benefits (maybe doctors will stop giving people strong psychiatric medications just because their football team made the Super Bowl).

When I was done, I went back to the corner office and submitted everything to the Institutional Review Board. Then I sat back and hoped for the best. Like an idiot.

October 2014

The big day arrived. The IRB debated the merits of my study, examined the risks, and… sent me a letter pointing out several irregularities in my consent forms.

IRREGULARITY #1: Consent forms traditionally included the name of the study in big letters where the patient could see it before signing. Mine didn't. Why not?

Well, because in questionnaire-based psychological research, you *never* tell the patient what you're looking for before they fill out the questionnaire. That's like Methods 101. The name of my study was "Validity Of A Screening Instrument For Bipolar Disorder". Tell the patient it's a study about bipolar disorder, and the gig is up.

The IRB listened patiently to my explanation, then told me that this was not a legitimate reason not to put the name of the study in big letters on the consent form. Putting the name of the study on the consent form was important. You know who *else* didn't put the name of the study on his consent forms? *Hitler.*

IRREGULARITY #2: Consent forms traditionally included a paragraph about the possible risks of the study and a justification for why we believed that the benefits were worth the risks. Everyone else included a paragraph about this on our consent forms, and read it to their patients before getting their consent. We didn't have one. Why not?

Well, for one thing, because all we were doing was asking them whether they felt happy and then sad sometimes. This is the sort

of thing that goes on every day in a psychiatric hospital. Heck, the other psychiatrists were using this same screening test, except *for real*, and they never had to worry about whether it had risks. In the grand scheme of things, this just wasn't a very risky procedure.

Also, psychiatric patients are sometimes… how can I put this nicely?… a little paranoid. Sometimes you can offer them breakfast and they'll accuse you of trying to poison them. I had no illusions that I would get every single patient to consent to this study, but I felt like I could at least avoid handing them a paper saying "BY THE WAY, THIS STUDY IS FULL OF RISKS".

The IRB listened patiently to my explanation, then told me that this was not a legitimate reason not to have a paragraph about risks. We should figure out some risks, then write a paragraph explaining how those were definitely the risks and we took them very seriously. The other psychiatrists who used this test every day didn't have to do that *because they weren't running a study*.

IRREGULARITY #3: Signatures are traditionally in pen. But we said our patients would sign in pencil. Why?

Well, because psychiatric patients aren't allowed to have pens in case they stab themselves with them. I don't get why stabbing yourself with a pencil is any less of a problem, but the rules are the rules. We asked the hospital administration for a one-time exemption, to let our patients have pens just long enough to sign the consent form. Hospital administration said absolutely not, and they

didn't care if this sabotaged our entire study, it was pencil or nothing.

The IRB listened patiently to all this, then said that it had to be in pen. You know who *else* had people sign consent forms in pencil…?

I'm definitely not saying that these were the only three issues the IRB sprung on Dr. W and me. I'm saying these are a *representative sample*. I'm saying I spent several weeks relaying increasingly annoyed emails and memos from myself to Dr. W to the IRB to the lady in the corner office to the IRB again. I began to come home later in the evening. My relationships suffered. I started having dreams about being attacked by giant consent forms filled out in pencil.

I was about ready to give up at this point, but Dr. W insisted on combing through various regulations and talking to various people, until he discovered some arcane rule that certain very safe studies with practically no risk were allowed to use an "expedited consent form", which was a lot like a normal consent form but didn't need to have things like the name of the study on it. Faced with someone even more obsessive and bureaucratic than they were, the IRB backed down and gave us preliminary permission to start our study.

The next morning, screening questionnaire in hand, I showed up at the hospital and hoped for the best. Like an idiot.

November 2014

Things progressed slowly. It turns out a lot of psychiatric inpatients are either depressed, agitated, violent, or out of touch with reality, and none of these are really conducive to wanting to participate in studies. A few of them already delusionally thought we were doing experiments on them, and got confused when we suddenly asked them to consent. Several of them made it clear that they hated us and wanted to thwart us in any way possible. After a week, I only had three data points, instead of the ten I'd been banking on.

"Data points" makes it sound abstract. It wasn't. I had hoped to put the results in the patients' easily accessible online chart, *the same place everyone else put the results of the exact same bipolar screening test* when they did it for real. They would put it in a section marked TEST RESULTS, which was there to have a secure place where you could put test results, and where everybody's secure test results were kept.

The IRB would have none of this. Study data are Confidential and need to be kept Secure. Never mind that all the patients' *other* secure test results were on the online chart. Never mind that the online chart contains all sorts of stuff about the patients' diagnoses, medications, hopes and fears, and even (remember, this is a psych hospital) secret fetishes and sexual perversions. Study data needed to be encrypted, then kept in a Study Binder in a locked drawer in a locked room that nobody except the study investigators had access to.

The first problem was that nobody wanted to give us a locked room that nobody except us had access to. There was a sort of All Purpose Psychiatry Paperwork room, but the janitors went in to clean it out every so often, and apparently this made it unacceptable. Hospitals aren't exactly drowning in spare rooms that not even janitors can get into. Finally Dr. W grudgingly agreed to keep it in his office. This frequently meant I couldn't access any of the study material because Dr. W was having important meetings that couldn't be interrupted by a resident barging into his office to rummage in his locked cabinets.

But whatever. The bigger problem was the encryption. There was a very specific way we had to do it. We would have a Results Log, that said things like "Patient 1 got a score of 11.5 on the test". And then we'd have a Secret Patient Log, which would say things like "Patient 1 = Bob Johnson from Oakburg." That way nobody could steal our results and figure out that Bob was sometimes happy, then sad.

(meanwhile, all of Bob's actual diagnoses, sexual fetishes, etc were in the easily-accessible secure online chart that we were banned from using)

And then – I swear this is true – we had to keep the Results Log and the Secret Patient Log right next to each other in the study binder in the locked drawer in the locked room.

I wasn't sure I was understanding this part right, so I asked Dr. W whether it made sense, to him, that we put a lot of effort writing

our results in code, and then put the key to the code in the same place as the enciphered text. He cheerfully agreed this made no sense, but said we had to do it or else our study would fail an audit and get shut down.

January 2015

I'd planned to get a hundred data points in three months. Thanks to constant bureaucratic hurdles, plus patients being less cooperative than I expected, I had about twenty-five. Now I was finishing my rotation on Dr. W's team and going to a clinic far away. What now?

A bunch of newbies were going to be working with Dr. W for the next three months. I hunted them down and threatened and begged them until one of them agreed to keep giving patients the bipolar screening test in exchange for being named as a co-author. Disaster averted, I thought. Like an idiot.

Somehow news of this arrangement reached the lady in the corner office, who asked whether the new investigator had completed her Pre-Study Training. I protested that she wasn't designing the study, she wasn't conducting any analyses, all she was doing was asking her patients the same questions that she would be asking them anyway as part of her job for the next three months. The only difference was that she was recording them and giving them to me.

The lady in the corner office wasn't impressed. You know who *else* hadn't thought his lackeys needed to take courses in research ethics?

So the poor newbie took a course on how Nazis were bad. Now she could help with the study, right?

Wrong. We needed to submit a New Investigator Form to the IRB and wait for their approval.

Two and a half months later, the IRB returned their response: Newbie was good to go. She collected data for the remaining two weeks of her rotation with Dr. W before being sent off to another clinic just like I was.

July 2015

Dr. W and I planned ahead. We had figured out which newbies would be coming in to work for Dr. W three months ahead of time, and gotten them through the don't-be-a-Nazi course and the IRB approval process just in time for them to start their rotation. Success!

Unfortunately, we received another communication from the IRB. Apparently we were allowed to use the expedited consent form to get consent for our *study*, but not to get consent to *access protected health information*. That one required a whole different consent

form, list-of-risks and all. We were right back where we'd started from.

I made my case to the Board. My case was: we're not looking at any protected health information, f@#k you.

The Board answered that we were accessing the patient's final diagnosis. It said right in the protocol, we were giving them the screening test, then comparing it to the patient's final diagnosis. "Psychiatric diagnosis" sure *sounds* like protected health information.

I said no, you don't understand, we're the psychiatrists. Dr. W is the one making the final diagnosis. When I'm on Dr. W's team, I'm in the room when he does the diagnostic interview, half the time I'm the one who types the final diagnosis into the chart. These are *our patients*.

The Board said this didn't matter. We, as the patient's doctors, would make the diagnosis and write it down on the chart. But we (as study investigators) needed a full signed consent form before we were allowed to access the diagnosis we had just made.

I said wait, you're telling us we have to do this whole bureaucratic rigamarole with all of these uncooperative patients before we're allowed to see something we wrote ourselves?

The Board said yes, exactly.

I don't remember this part very well, except that I think I half-heartedly trained whichever poor newbie we were using that month in how to take a Protected Health Information Consent on special Protected Health Information Consent Forms, and she nodded her head and said she understood. I think I had kind of clocked out at this point. I was going off to work all the way over in a different town for a year, and I was just sort of desperately hoping that Dr. W and various newbies would take care of things on their own and then in a year when I came back to the hospital I would have a beautiful pile of well-sorted data to analyze. Surely trained doctors would be able to ask simple questions from a screening exam on their own without supervision, I thought. Like an idiot.

July 2016

I returned to my base hospital after a year doing outpatient work in another town. I felt energized, well-rested, and optimistic that the bipolar screening study I had founded so long ago had been prospering in my absence.

Obviously nothing remotely resembling this had happened. Dr. W had vaguely hoped that I was taking care of it. I had vaguely hoped that Dr. W was taking care of it. The various newbies whom we had strategically enlisted had either forgotten about it, half-heartedly screened one or two patients before getting bored, or else mixed up the growing pile of consent forms and releases and logs so thoroughly that we would have to throw out all their work. It had

been a year and a half since the study had started, and we had 40 good data points.

The good news was that I was back in town and I could go back to screening patients myself again. Also, we had some particularly enthusiastic newbies who seemed really interested in helping out and getting things right. Over the next three months, our sample size shot up, first to 50, then to 60, finally to 70. Our goal of 100 was almost in sight. The worst was finally behind me, I hoped. Like an idiot.

November 2016

I got an email saying our study was going to be audited.

It was nothing personal. Some higher-ups in the nationwide hospital system had decided to audit every study in our hospital. We were to gather all our records, submit them to the auditor, and hope for the best.

Dr. W, who was obsessive-compulsive at the best of times, became unbearable. We got into late-night fights over the number of dividers in the study binder. We hunted down every piece of paper that had ever been associated with anyone involved in the study in any way, and almost came to blows over how to organize it. I started working really late. My girlfriend began to doubt I actually existed.

The worst part was all the stuff the newbies had done. Some of them would have the consent sheets numbered in the upper left-hand-corner instead of the upper-right-hand corner. Others would have written the patient name down on the Results Log instead of the Secret Code Log right next to it. One even wrote something in green pen on a formal study document. It was hopeless. Finally we just decided to throw away all their data and pretend it had never existed.

With that decision made, our work actually started to look pretty good. As bad as it was working for an obsessive-compulsive boss in an insane bureaucracy, at least it had the advantage that – when nitpicking push came to ridiculous shove – you were going to be super-ready to be audited. I hoped. Like an idiot.

December 2016

The auditor found twenty-seven infractions.

She was very apologetic about it. She said that was actually a pretty good number of infractions for a study this size, that we were actually doing pretty well compared to a lot of the studies she'd seen. She said she absolutely wasn't going to shut us down, she wasn't even going to censure us. She just wanted us to make twenty-seven changes to our study and get IRB approval for each of them.

I kept the audit report as a souvenier. I have it in front of me now. Here's an example infraction:

> The data and safety monitoring plan consists of 'the Principal Investigator will randomly check data integrity'. This is a prospective study with a vulnerable group (mental illness, likely to have diminished capacity, likely to be low income) and, as such, would warrant a more rigorous monitoring plan than what is stated above. In addition to the above, a more adequate plan for this study would also include review of the protocol at regular intervals, on-going checking of any participant complaints or difficulties with the study, monitoring that the approved data variables are the only ones being collected, regular study team meetings to discuss progress and any deviations or unexpected problems. Team meetings help to assure participant protections, adherence to the protocol. Having an adequate monitoring plan is a federal requirement for the approval of a study. See Regulation 45 CFR 46.111 Criteria For IRB Approval Of Research. IRB Policy: PI Qualifications And Responsibility In Conducting Research. Please revise the protocol via a protocol revision request form. Recommend that periodic meetings with the research team occur and be documented.

Among my favorite other infractions:

1. The protocol said we would stop giving the screening exam to patients if they became violent, but failed to rigorously define "violent".

2. We still weren't educating our patients enough about "Alternatives To Participating In This Study". The auditor agreed

that the only alternative was “not participating in this study”, but said that we had to tell every patient that, then document that we’d done so.

3. The consent forms were still getting signed in pencil. We are never going to live this one down. If I live to be a hundred, representatives from the IRB are going to break into my deathbed room and shout “YOU LET PEOPLE SIGN CONSENT FORMS IN PENCIL, HOW CAN YOU JUSTIFY THAT?!”

4. The woman in the corner office who kept insisting everybody take the Pre-Study Training… hadn’t taken the Pre-Study Training, and was therefore unqualified to be our liaison with the IRB. I swear I am not making this up.

Faced with submitting twenty-seven new pieces of paperwork to correct our twenty-seven infractions, Dr. W and I gave up. We shredded the patient data and the Secret Code Log. We told all the newbies they could give up and go home. We submitted the Project Closure Form to the woman in the corner office (who as far as I know still hasn’t completed her Pre-Study Training). We told the IRB that they had won, fair and square; we surrendered unconditionally.

They didn’t seem the least bit surprised.

August 2017

I’ve been sitting on this story for a year. I thought it was unwise to publish it while I worked for the hospital in question. I still think it’s

a great hospital, that it delivers top-notch care, that it has amazing doctors, that it has a really good residency program, and even that the Research Department did everything it could to help me given the legal and regulatory constraints. I don't want this to reflect badly on them in any way. I just thought it was wise to wait a year.

During that year, Dr. W and I worked together on two less ambitious studies, carefully designed not to require any contact with the IRB. One was a case report, the other used publicly available data.

They won 1st and 2nd prize at a regional research competition. I got some nice certificates for my wall and a little prize money. I went on to present one of them at the national meeting of the American Psychiatric Association, a friend helped me write it up formally, and it was recently accepted for publication by a medium-tier journal.

I say this not to boast, but to protest that I'm not as much of a loser as my story probably makes me sound. I'm capable of doing research, I think I have something to contribute to Science. I still think the bipolar screening test is inappropriate for inpatient diagnosis, and I still think that patients are being harmed by people's reliance on it. I still think somebody should look into it and publish the results.

I'm just saying it's not going to be me. I am *done* with research. People keep asking me "You seem really into science, why don't you become a researcher?" Well…

I feel like a study that realistically could have been done by one person in a couple of hours got dragged out into hundreds of hours of paperwork hell for an entire team of miserable doctors. I think its scientific integrity was screwed up by stupid requirements like the one about breaking blinding, and the patients involved were put through unnecessary trouble by being forced to sign endless consent forms screaming to them about nonexistent risks.

I feel like I was dragged almost to the point of needing to be in a psychiatric hospital myself, while my colleagues who just *used* the bipolar screening test – without making the mistake of trying to check if it works – continue to do so without anybody questioning them or giving them the slightest bit of aggravation.

I feel like some scientists do amazingly crappy studies that couldn't possibly prove anything, but get away with it because they have a well-funded team of clerks and secretaries who handle the paperwork for them. And that I, who was trying to do everything right, got ground down with so many pointless security-theater-style regulations that I'm never going to be able to do the research I would need to show they're wrong.

In the past year or so, I've been gratified to learn some other people are thinking along the same lines. Somebody linked me to The Censor's Hand, a book by a law/medicine professor at the University of Michigan. A summary from a review:

> Schneider opens by trying to tally the benefits of IRB review. "Surprisingly," he writes, a careful review of the literature

suggests that “research is not especially dangerous. Some biomedical research can be risky, but much of it requires no physical contact with patients and most contact cannot cause serious injury. Ill patients are, if anything, safer in than out of research.” As for social-science research, “its risks are trivial compared with daily risks like going online or on a date.”

Since the upsides of IRB review are likely to be modest, Schneider argues, it’s critical to ask hard questions about the system’s costs. And those costs are serious. To a lawyer’s eyes, IRBs are strangely unaccountable. They don’t have to offer reasons for their decisions, their decisions can’t be appealed, and they’re barely supervised at the federal level. That lack of accountability, combined with the gauzy ethical principles that govern IRB deliberations, is a recipe for capriciousness. Indeed, in Schneider’s estimation, IRBs wield coercive government power—the power to censor university research—without providing due process of law.

And they’re not shy about wielding that power. Over time, IRB review has grown more and more intrusive. Not only do IRBs waste thousands of researcher hours on paperwork and elaborate consent forms that most study participants will never understand. Of greater concern, they also superintend research methods to minimize perceived risks. Yet IRB members often aren’t experts in the fields they oversee. Indeed, some know little or nothing about research methods at all.

> IRBs thus delay, distort, and stifle research, especially research on vulnerable subgroups that may benefit most from it. It's hard to precise about those costs, but they're high: after canvassing the research, Schneider concludes that "IRB regulation annually costs thousands of lives that could have been saved, unmeasurable suffering that could have been softened, and uncountable social ills that could have been ameliorated."

This view seems to be growing more popular lately, and has gotten support from high-profile academics like Richard Nisbett and Steven Pinker:

> Should IRBs (human subjects research approval committees) be dismantled? [Probably yes.] http://t.co/5mxhEycEA5
>
> — Steven Pinker (@sapinker), July 24, 2015

And there's been some recent reform, maybe. The federal Office for Human Research Protections made a vague statement that perhaps studies that obviously aren't going to hurt anybody might not need the full IRB treatment. There's still a lot of debate about how this will be enforced and whether it's going to lead to any real-life changes. But I'm glad people are starting to think more about these things.

(I'm also glad people are starting to agree that getting rid of a little oversight for the lowest-risk studies is a good compromise, and that we don't have to start with anything more radical.)

I sometimes worry that people misunderstand the case against bureaucracy. People imagine it's Big Business complaining about the regulations preventing them from steamrolling over everyone else. That hasn't been my experience. Big Business – heck, Big Anything – loves bureaucracy. They can hire a team of clerks and secretaries and middle managers to fill out all the necessary forms, and the rest of the company can be on their merry way. It's everyone else who suffers. The amateurs, the entrepreneurs, the hobbyists, the people doing something as a labor of love. Wal-Mart is going to keep selling groceries no matter how much paperwork and inspections it takes; the poor immigrant family with the backyard vegetable garden might not.

Bureaucracy in science does the same thing: limit the field to big institutional actors with vested interests. No amount of hassle is going to prevent the Pfizer-Merck-Novartis Corporation from doing whatever study will raise their bottom line. But enough hassle *will* prevent a random psychiatrist at a small community hospital from pursuing his pet theory about bipolar diagnosis. The more hurdles we put up, the more the scientific conversation skews in favor of Pfizer-Merck-Novartis. And the less likely we are to hear little stuff, dissenting voices, and things that don't make anybody any money.

I'm not just talking about IRBs here. I could write a book about this. There are so many privacy and confidentiality restrictions

around the most harmless of datasets that research teams won't share data with one another (let alone with unaffiliated citizen scientists) lest they break some arcane regulation or other. Closed access journals require people to pay thousands of dollars in subscription fees before they're allowed to read the scientific literature; open-access journals just shift the burden by requiring scientists to pay thousands of dollars to publish their research. Big research institutions have whole departments to deal with these kinds of problems; unaffiliated people who just want to look into things on their own are out of luck.

And this is happening at the same time we're becoming increasingly aware of the shortcomings of big-name research. Half of psychology studies fail replication; my own field of psychiatry is even worse. And citizen-scientists and science bloggers are playing a big part in debunking bad research: here I'm thinking especially of statistics bloggers like Andrew Gelman and Daniel Lakens, but there are all sorts of people in this category. And both Gelman and Lakens are PhDs with institutional affiliations – "citizen science" doesn't mean random cavemen who don't understand the field – but they're both operating outside their day job, trying to contribute a few hours per project instead of a few years. I know many more people like them – smart, highly-qualified, but maybe not going to hire a team of paper-pushers and spend thousands of dollars in fees in order to say what they have to say. Even now these people are doing great work – but I can't help but feel like more is possible.

IRB overreach is a small part of the problem. But it's the part which sunk my bipolar study, a study I really cared about. I'm excited that there's finally more of a national conversation about this kind of thing, and hopeful that further changes will make scientific efforts easier and more rewarding for the next generation of doctors.