How Human Subjects Research Rules Mislead You and Your University, and What to Do About it[1]

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Abstract

Universities require faculty and students planning research involving human subjects to pass formal certification tests and then submit research plans for prior approval. Those who diligently take the tests may better understand certain important legal requirements but, at the same time, are often misled into thinking they can apply these rules to their own work which, in fact, they are not permitted to do. They will also be missing many other legal requirements not mentioned in their training but which govern their behaviors. Finally, the training leaves them likely to completely misunderstand the essentially political situation they find themselves in. The resulting risks to their universities, collaborators, and careers may be catastrophic, in addition to contributing to the more common ordinary frustrations of researchers with the system. To avoid these problems, faculty and students conducting research about and for the public need to understand that they are public figures, to whom different rules apply, ones that political scientists have long studied. University administrators (and faculty in their part-time roles as administrators) need to reorient their perspectives as well. University research compliance bureaucracies have grown, in well-meaning but sometimes unproductive ways that are not required by federal laws or guidelines. We offer advice to faculty and students for how to deal with the system as it exists now, and suggestions for changes in university research compliance bureaucracies, that should benefit faculty, students, staff, university budgets, and our research subjects.

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If you conduct research involving human subjects at a U.S. college or university, you are almost surely required to study applicable laws, guidelines, ethics, histories, and Institutional Review Board (IRB) pre-approval procedures. You also will have obtained formal certification of your knowledge by taking several tests, complete with minimum acceptable grades on each. These extraordinary procedures -- which stem from historical abuses of governmental power in the name of clinical research and recent increases in public concerns about privacy -- teach a small subset of applicable law and mislead about most of the politics. This is all the more problematic because, as we explain below, no federal law or rule compels your university to make you take this training. Universities should eliminate these misleading rules but, until they do, optimizing for your career, your university, and your collaborators strongly suggests taking a political science perspective in learning how to act when conducting research involving human subjects. University research compliance institutions, which have generated considerable consternation among researchers, could use a similar reorientation (indeed, "horror stories abound," AAUP, 2013; see also Klitzman, 2015 and Schneider, 2015). We show how.

Human subject certification supposedly teaches faculty, students, and staff what types of research are permissible. As a result, you may think you are safe making independent decisions about what research you are allowed to conduct, which research projects require IRB approval, and the set of laws that govern your research conduct. You're not. If you act on this basis, you are making a major mistake that could have potentially serious career ramifications. Not only are the rules too complicated and nuanced to be applied by a non-expert even with the training, but federal guidelines indicate that the researcher is not permitted to be the one to apply them. What? That's right, *your university requires that you be tested on your knowledge of rules that, if you apply in practice, guarantee you'll be in violation*.[4] Moreover, most of the rules governing your research are not even mentioned in these certification tests. In other words, paying closer attention to the required training, and learning what is and isn't human subjects research, may lead you to think you can make these decisions yourself and so, paradoxically, will likely *increase* the probability of doing the wrong thing and getting you and your university into trouble, or worse.

What should *you* do about this? If you make the decision on your own, you are of course OK if no one questions you about it. However, if the appropriateness of your work is raised at some point, what

[4] "OHRP's [the federal Office of Human Research Protections] long-standing recommendation is that investigators not be given the authority to make an independent determination that [their] human subjects research is exempt." (http://j.mp/hhsExempt), to which most universities have responded by formally prohibiting their faculty and students from making their own determination. For example, Harvard's rules read "Investigators may not decide for themselves that their own (or their students') research projects involving human subjects are exempt" (http://j.mp/huRules, §7.2). See also Ritter et al. (2013).

will protect you is prior written approval, not whether you (the person whose behavior is being judged) can come up with a post hoc justification for how your behavior fits the rules you learned on these tests.

A Political Science Perspective on Human Subjects Research

That social scientists need to pay attention to politics before they even start studying the world may be disconcerting but it should be no surprise: political scientists have shown in numerous areas that wherever there are people, there is politics. In this case, politics affects your research, what research you will be allowed to conduct by your university, whether you will get into trouble or are safe in doing this research, whether your university will back you up, and whether your research or career will be advanced, sidetracked, or terminated.

As academics, we are not private citizens; we are public figures -- representing our universities and governments, receiving public money in research grants, housed at institutions supported by taxpayer dollars via federal overhead and sometimes direct governmental subventions, writing for a broad audience larger than we know personally, and doing research of at least occasional intense public interest. As a public figure, researchers could follow, with little change, how political scientist Richard Fenno (1976: 131) described best practices among members of Congress: "To neutralize the opposition is to stop them from talking against you. It is to win their silence, not their support… it makes sense for every House member to allocate some time to a strategy of neutralization" (1976: 131).

Scholars are always encouraged to think defensively -- to imagine that after publication there will be, out there somewhere, a graduate student grasping a yellow pad of paper with your name scribbled across the top. To act in our personal interest as public figures, we also need to imagine that there's a reporter out there with a similar pad of paper, determined to write a critical article about your use of human subjects in research. There may well also be an enterprising politician or prosecutor thinking of ways to advance their career objectives without regard for the potential collateral damage to your research or career. If you follow the news, you know this happens; if you think it can't happen to you because you are "careful" or have an "explanation," just think about what happens in politics to public figures all the time. For one example where the problem directly affects scholarly research, consider that "The history of public policy experiments is littered with [scholarly] evaluations torpedoed by politicians appropriately attentive to the short-term desires of their constituents, such as those who wind up in control groups without new services or who cannot imagine why a government would randomly assign citizens to government programs" (King et al., 2007).

Of course, the vast majority of journalists are responsible professionals, and politicians are not generically out to get you. But, as political science teaches, political actors are out to advance their own interests, and your personal goals and reputation may not even appear in their calculations. These consequences may not be common, but you don't buy flood insurance for sunny days either. Moreover, the issue is not merely rogue journalists or aspiring politicians: your own university is likely to judge your research differently depending on the political environment in which you propose to conduct it. University IRBs and associated offices rarely only pay attention to their narrowly defined official legal responsibilities.

Only Written Approval Protects You

You might think that you would be defenseless faced with a journalist determined to write a negative article about you, or an aspiring prosecutor interpreting the laws governing human subjects research differently than you, or a politician trying to get elected by making an example of some academic or university -- but this is untrue. Your university has a whole infrastructure designed to protect you; you just need to learn how to use it, since you will not have been taught this in your human subjects training. Of course, outside actors are free to write whatever they like, but many university procedures are designed to offload the responsibility for important decisions about the appropriateness of your research from you to your university. Your responsibility then is to make the proposal, get approval, and follow the plan you set out.

For example, have you ever obtained data from an outside organization, signed an agreement governing how you will use it, and agreed to terms that put you at legal or financial risk if there's a problem? If so, big mistake. Your university employs lawyers who will read and negotiate data use agreements for you and will sign them on behalf of the university -- if you ask. If you do, this means that your university rather than you personally will bear the legal or financial risk if something goes wrong. Similarly, if you have written approval from your university to conduct your research, and a journalist has a beef with what you did, they are then at least supposed to raise it with the university, and you'd be on firm ground telling them to do so.

However, you cannot guarantee that your university's administrators will in fact back you up unless you previously obtained prior written documentation that you followed university rules. At least with respect to how you treat human subjects, this normally means a simple letter from the IRB or other responsible official. When? Always. For all your research -- even if you think it is obvious that your research is in compliance with all rules. If a university official tells you that you needn't apply formally,

send him or her an email with your understanding and ask for confirmation by return email. Keep the email. Of course, you also don't need to be a pest; people in your IRB office have a difficult job and work hard to balance institutional compliance and faculty satisfaction. To help both them and you, contact the IRB early in the process and stay in close touch for complicated cases or if your plans change; when possible, try to combine many similar research ideas into a single broad request; and provide enough detail so that they don't have to iterate with you too many times. If you do get approval, be sure to follow the approved protocols when you actually carry out the research.

But isn't it true, according to IRB rules, that you can decide whether human subject laws apply to your research, without formal approval? Formally, no. Almost all universities have rules against you making this decision independently. But in practice, yes -- *if* you interpret the law correctly *and* no one questions your decision. However, if anyone questions your decision, even if it would stand up in every court in the country, then it is your interpretation versus theirs. You don't need to ask for human subjects approval if all you want to do is prove a mathematical theorem; however, if you find yourself anywhere remotely near the vast gray area, do not make the decision yourself. In the public sphere especially, formal approval will help, even if it was screamingly clear to you from the outset that you were right. We know from considerable social-psychological evidence that it is all too easy to come up with just so stories that justify one's own behavior. After all, the issue is not whether you can justify your behavior; the issue is whether a reporter or someone else can make an argument that what you did is inappropriate. The vast gray area moves all the time. In politics, the truth is merely one of many considerations. Ethical arguments can always be countered by an equally emphatic opposing argument, and so once you begin mud wrestling with a reporter on deadline about the intricacies of IRB rules, federal guidelines, legal precedence, and the details of your research design, success is not an option.

After all, does there exist *any* position on any issue for which it would be impossible to create a compelling political argument? Before you answer, recall that the most important electoral decisions made by this country have been fought over whether we should have a constitutional amendment against burning the American flag, whether the Romney Health Care plan and the nearly identical Obama health care plan were indeed identical or not, and the disposition of Quemoy and Matsu (which few can locate on a map and fewer have visited). Even scientific facts melt into arguments on both sides in the political sphere. So don't fool yourself into thinking, just because you can explain your decisions after the fact, that they can't be made into political issues by a creative reporter, advocate, or someone else with interests divergent from yours. Unfortunately, the psychological evidence seems to be that you will ignore the political evidence, and so be more careful than you think is necessary, even after adjusting for the fact that you think you have been (Banaji and Greenwald, 2013).

To avoid these problems, and to stay above the fray where your research belongs, you obviously need to follow the rules, but you also need written approval. If you have that piece of paper, merely explain to the reporter or politician that you followed university rules and, if he doesn't like the rules or the university's decision in this case, you can send him to go talk to university officials (and, implicitly, leave you alone). But if you don't have the piece of paper, you will start sinking back into the mud where anything you say will sound self-serving or irrelevant, and at the same time your university will the first *begin* to make a decision about whether to defend you. You don't want that decision made in the midst of a media firestorm: Any reasonable reading of the political science literature indicates that university officials, like everyone else, are political actors too.

Moreover, without written documentation, you leave a reporter able to write, after making a tendentious argument about your supposedly unethical behavior, that you didn't even follow your own university's rules. In politics, being confident that you will always be able to win any legal or procedural claim of impropriety is just delusional. To avoid the unnecessary hit your career would take, and the damage you would do to your institution and colleagues, follow the political rules that good public figures follow, not the incomplete and misleading legal rules you may have learned while getting certified for human subjects research.

Most of the Rules that Apply to You Were Not on the Test

You weren't told this in your formal training, but formal IRB approval of your research protocol does *not* give you approval to carry out your research. You must also satisfy many other rules, often less visible, and most not covered by the IRB but every bit as important as human subject rules. Scholarly research is a heavily regulated industry, even aside from rules about human subjects. For a few examples of both broad and specific types, consider that your research must not violate rules regarding trademarks, copyrights, proprietary information, national security interests, export controls, human resources (of your research assistants, employees, or even temporary workers like on Amazon's Mechanical Turk), conflicts of interest, information security, financial spending, stem cells, animal care, biosafety, environmental health, clinical patient care, and others. Moreover, regardless of the official rules, most universities will prevent you from conducting your research if they decide that the headline risk or other risks are too great. This may come as a surprise, but the IRB only covers one aspect of your research. The usual informal procedure in fact is for IRB officials to inform the office of the provost or president in your university, often without telling you, about research that might have higher than usual political risk; they may then make a decision about your work.

Staff at your university's IRB or sponsored research office, who happen to notice that one of these other issues are implicated in your research, may refer you to other relevant university offices, but in the absence of any formal approval mechanism, analogous to the IRB for human subjects rules, negotiating these waters is your responsibility. Getting formal IRB approval is crucial, but wholly insufficient. As a public figure and representative of your university and yourself, you are the one standing behind your research. You can't shirk from that responsibility as you'll be held to a high standard for it.

If there is ambiguity remaining, a sometimes useful strategy is to develop and announce some new rules and follow them too, just to make sure -- and to convey publicly -- that you are nowhere near the line. For example, when King, Pan, and Roberts (2014) proposed surreptitiously downloading millions of social media posts before the Chinese government could censor them, creating hundreds of pseudonymous accounts on local social media websites all over China, randomly assigning numerous artificial posts they wrote to support or oppose the government or collective action, and then setting up their own social media site under pseudonyms to help reverse engineer how censorship happened, their IRB declared this as "not human subjects research." As this seemed like an extreme situation, they commented in their article (fn 20), "We also added our own ethics rules, not required by the IRB, which dictate that we avoid, wherever possible, influencing or disturbing the system we are studying (see our supplementary appendix). The similarity to the Prime Directive in *Star Trek* notwithstanding, this seems like the appropriate stance for scientists attempting to understand the world, as distinct from advocates trying to change it, and in any event is more likely to yield reliable inferences." Neither the IRB nor anyone else required these extra rules, but the research was potentially incendiary, and so adding additional rules made it even more unambiguous that they were not near the line.

Advice for Universities

University research compliance operations have grown over time as a series of incremental, risk adverse responses to laws passed by congress, and interpretations by federal agencies and courts in the form of formal rules, opinions, informal guidance, even more informal reports, web sites, and FAQs. Faculty and students need to adapt to the system as it exists. However, it is time that university administrators -- in partnership with faculty, in their part time roles as administrators -- begin to rethink the whole system of research compliance within universities, rather than continue to build it incrementally, so they can better accomplish their institution's goals. In our view, this involves changing university procedures to better align university and researcher interests. Crucially, these changes can be made now as they require *no*

changes in federal law. We suggest three specific innovations which when implemented should greatly improve organizational efficiency, and reduce faculty and student frustrations, wasted time, budgetary resources, faculty and institutional risk, and noncompliance.

First, universities should *eliminate the requirement that researchers be tested on human subject laws*. Nothing in federal law indicates that universities must require researchers to take these tests.[5] Universities have chosen to require these tests mostly because all the other universities adopted them, but no rule or law prevents them from being eliminated immediately. Faculty and students conducting research are in fact required to follow rules, and so it is reasonable to ask how they will do this. As it turns out, this is easy. To begin, recognize that faculty are capable of learning on their own, and teaching their students on their own; this is, after all, what they do for a living. Help them by offering some suggested reading materials, customized based on the type of research each conducts; explain that it is their responsibility to learn this material; and ask them to confirm (perhaps even with a formal signature) that they have studied relevant laws and will ask a specific university official (about which see below) if they have any questions before research commences.

After all, no systematic evidence exists that the tests accomplish their stated purpose, and there is much reason to think that they fail at best or are counterproductive at worst. For one, from our informal surveys, it appears that most faculty and students actually cheat on these tests (in ways that are obvious to those who take them, but which we will not describe here), and so the intended knowledge transfer likely does not occur. For another, as we explain above, the more researchers do pay attention and receive the intended information, the more faculty and students will be likely to make the wrong decisions and to act in ways that put themselves and their institutions at considerable and unnecessary risk.

To see the problems with the tests, consider the following thought experiment. Take a large group of incoming graduate students during the first week of classes and randomly assign half to take the humans subjects research training and tests. Assign the other half unrelated web training and tests, such as about statistical methods. Then show all the students a series of research proposals that fit each of the formal research categories and ask whether they should seek formal approval. As we have shown in this essay, from their perspective and that of their university, the correct answer in every case is that they should seek (written) approval. However, from all that social scientists have learned about survey research, it seems obvious that those who took the human subjects training will assume they did so for a

[5] "The HHS regulations for the protection of human subjects (45 CFR part 46, http://j.mp/HHSregs) do not require investigators to obtain training in the protection of human subjects in research." http://j.mp/HHS-faq. Even the National Institutes of Health (NIH), which explicitly requires researchers submitting grant proposals to receive "education on the protection of human research participants," emphasizes that they will not declare what constitutes "education"; for example,"The NIH does not plan to issue a list of 'endorsed' programs" (http://j.mp/NIHed).

reason and thus conclude that they needn't seek approval for research falling into some of the formal categories, such as "not human subjects" or "exempt". Perhaps those who also read our essay will be less likely to make this mistake. But even better would be to not require a misguided tests like this in the first place.

Those appointed to university leadership roles endeavor to be good stewards and act responsibly, but sometimes getting out in the lead, and doing something more in their interests and that of their faculty and students, is far safer than following along with the pack. We encourage some to take that leadership role.

Second, universities should *establish a single point of contact* (perhaps called the university "research compliance office") through which all research approvals should flow. This office would provide much quicker and easier approvals, perhaps involving a simple phone call, followed up by a brief email, encouraging faculty to routinely obtain written approval for a wider range of research, without expecting them to become experts on the intricacies of all the rules for which universities have been required to hire experts. This single point of contact would cover all relevant rules, not only those pertaining to human subjects. This research compliance office would then refer the researcher to other relevant university units, require follow up, make sure that responses were timely, work with the researcher, and get to an agreed upon research plan.

The research compliance office would be directed by one person with responsibility, but it would be staffed by enough people to be able to take calls without delay. No (or few) new hires would be needed at most universities to accomplish this, since the office could be staffed by current employees now in other offices, such as the vice provost for research, sponsored research, IRB, general council, trademark office, among others. A unified website, with automated assistance, would also go a long way to speeding up the process and eliminating administrative burdens presently now in the way. Including information specifically tailored to social scientists and others submitting research protocols would also be very helpful. As much as researchers believe in their own ability to do what's right, they won't necessarily be able to predict what aspects of research will be problematic from a regulatory standpoint. They need this expertise right at the start, even before deciding which of the myriad issues may affect their proposed work and so which experts they should seek out. This is especially pertinent for first time users where help with complex issues such as informed consent, deception, and participant debriefing, and others would be helpful. Separating clinical and biomedical protocols from social science research proposals would also increase efficiency and reduce frustration. Is it really necessary for a political scientist to have to certify they are not using animals in their research, and are not prescribing drugs to human patients, every time they file for approval?

And finally, instead of long training sessions and formal tests, universities should *adopt a simple and powerful social contract* for faculty and students. If you work at the university, all research must be approved through the university research compliance office, the single point of contact. If a researcher seeks and obtains written approval, and then follows through and actually conducts the research as approved, the university will back them up. If they fail to obtain written approval, they're violating university rules and on their own if anything happens. This message is simple enough to put in hiring letters or in a short paragraph on department homepages, to supplement any required formal signatures where researchers testify to their learning the rules; we know from communications research that clear and simple messages, fully and obviously in the interests of recipients, are exactly those that are easiest to convey and most likely to be understood and followed.

Implementing these three rules would massively reduce frustrations so common now, save huge amounts of faculty, student, and staff time, reduce the risks to universities and their employees, increase the odds of compliance, and better align the interests of human subjects and the entire university community.

Concluding Remarks

Researchers sometimes view university rules as a nuisance and, indeed, vast improvements in the efficiency of research compliance procedures at many universities are sorely needed -- even beyond the fact that they unnecessarily require tests that mislead. However, the rules exist not only for the protection of human subjects, but also for the protection of the researcher. The political arrangement is that researchers keep lines of communication open to the appropriate university officials, get their advice, and in return receive their backing. Similarly, universities that adjust their rules as we describe will create a far more efficient and safer research environment for their faculty and students and for their institutions, and we strongly encourage them to do so.

We also urge faculty to get involved in encouraging their universities to change research compliance procedures as described. But regardless of the state of these procedures at your university, it still makes sense to act in your interests, and those of your university, by thinking like a political scientist and understanding your role as a public figure. Get approval, stick to the protocols you submitted, and get it in writing!

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