Clinical Research Ethics Question of the Month: Disqualifying Past Actions

By Norman M. Goldfarb

You are on a committee tasked with advising the FDA on whether certain past actions unrelated to clinical research should disqualify a physician from conducting clinical studies.

How serious does a past action have to be before it should disqualify a physician from conducting clinical studies?

Figure 1. Weighted Average Ratings of Offenses on 0-5 Scale (higher score means less serious offense disqualifies)

Based on weighted averages (0 for “irrelevant” up to 5 for “even a whiff”), the 140 respondents, on average, believe that child abuse (2.98), sexual misconduct (2.62), racist statement(s) (2.58), and a business relationship with an unsavory government (2.57) are the most serious offenses.

Respondents believe investment in a business that harms the environment (2.02), statements that an alien invasion is underway (2.16), being publicly drunk and disorderly (on personal time) (2.37), and an investment in a business that treats workers unfairly (2.28) are the least serious offenses.

Respondents believe a business relationship with an unsavory government to be a more serious offense (2.57) than investment in a business that treats workers unfairly (2.28), which, in turn, is a more serious offense than investment in a business that harms the environment (2.02).

Respondents believe illegal drug use (not affecting work) (2.51) is only a middling offense.
Some respondents believe that “even a whiff” of any of the actions should disqualify a physician from conducting clinical research. At the opposite extreme, some respondents believe that all the actions are “irrelevant.”

The actions with the highest “even a whiff” scores are child abuse (40%), sexual misconduct (24%), and racist statement(s) (19%).

The actions with the highest “irrelevant” scores are statements that an alien invasion is underway (35%), investment in a business that harms the environment (27%), and investment in a business that treats workers unfairly (20%).

The polarized opinions on child abuse suggest that some respondents might have misread the questions to ask whether any offense should be taken very seriously, instead of the actual question: whether an offense needs to be very serious to be disqualifying.

**Representative and Notable Comments by Respondents**

These actions demonstrate a lack of judgment that may, at some point, become relevant and impact that investigator’s integrity.

When you’re conducting a clinical trial, you need to have the highest level of ethics and values. If you make choices, even on personal time, that don’t reflect the high ethics and values we need to see in a clinical investigation, it draws into question the ability to stick to those ethics and values in the clinical setting.

How can we be sure publicly drunk and disorderly behavior or illegal drug use wouldn’t affect clinical trial conduct?

Any misconduct that results in significant legal disciplinary action should disqualify a physician from conducting research.

If known to the sponsor, even a whiff of a bad action would be damaging.
Unless there was direct involvement by the PI with regards to influencing these governments or companies, I can’t see holding the PI accountable.

The action must be intentional. Although unrelated to the clinical research work, it shows the doctor’s personal level of integrity and, if this is questionable, the risk of poor trial integrity increases.

Most of these actions are “social” and it depends on circumstances, when they occurred, and if they have been repeated or habitual. All lead to questioning a PI’s ethics and morals.

What about the PI that currently is exemplary in his/her conduct, while the past is shady? None of the actions would indicate that an investigator is unqualified, is indifferent to GCP, would falsify data, or would steal. They might get a person fired or incarcerated, but they do not affect the physician’s qualifications to conduct a clinical trial. I might not want to work with that person, but that is not the question posed.

Our society is currently obsessed with punishing people who have unpopular beliefs, opinions or habits. I would hope the FDA would stick to the letter of the law. If the physician did not break any laws in their dealings with an “unsavory government” or in their racist statements, then we step onto an impossibly slippery slope to demand the government strip them of their right to pursue their chosen career path. Maybe a medical licensing board can consider “moral” ramifications. Maybe an employer, an industry sponsor, or a grant-issuing committee can consider “objectivity” or “public relations” concerns. None of these should be within the purview of the FDA’s determination of the physician’s expertise in attempting to conduct clinical studies. As a compromise, maybe there is a mechanism where the FDA could release a nonbinding censure of the physician’s past activities, which outlines a specific objection, but also explains why it is not within the FDA’s scope to disqualify the physician solely on those grounds. Such an approach shines a light on the disconcerting behavior and may help dissuade others from similar actions, lest they wish to be similarly called out.

**Discussion**

Many authors, artists, government and business leaders, etc., who have made great contributions to society have been horrible people, as well. There is no settled judgment on whether their professional achievements should be considered in isolation from their personal failings.

This month’s question addresses potential FDA policies, not the policies of employers, state licensing boards, other government agencies, or society as a whole. The FDA’s charter is to ensure proper conduct of clinical research, so it should consider the actions in that light. While not within its purview, the FDA must also prefer that the public have confidence in the people who develop medical treatments. Past scandals have all involved actions directly related to the conduct of clinical trials, but one can imagine the headline, “Investigator in Pediatric Drug Study Has History of Child Molestation.”

Form FDA 1572 requires investigators to check a box to substantiate “education, training and experience that qualify the investigator as an expert in the clinical investigation of the drug for the use under investigation.” However, the form does not ask about potentially disqualifying actions, even those related to clinical research.

The FDA’s website states that it “may disqualify a clinical investigator if the clinical investigator has repeatedly or deliberately failed to comply with applicable regulatory requirements or the clinical investigator has repeatedly or deliberately submitted false information to the sponsor or, if applicable, to FDA, in any required report.” ([www.fda.gov/ICECI/EnforcementActions/ucm321308.htm](http://www.fda.gov/ICECI/EnforcementActions/ucm321308.htm))
The FDA prohibits debarred persons from any involvement with clinical research. The FDA reserves debarment for “firms or individuals convicted of a felony under Federal law for conduct (by a firm) relating to the development or approval, including the process for development or approval, of any abbreviated drug application; or (an individual convicted) for conduct relating to development or approval of any drug product, or otherwise relating to any drug product under the Federal Food, Drug, and Cosmetic Act.” (www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/complianceenforcement/default.htm)

IRBs have broad discretion to assess the risks of a clinical study. The U.S. Code of Federal Regulations (21 CFR 56.111(a)(2)) states that, for an IRB to approve a clinical study, it must find that “[r]isks to subjects are reasonable in relation to anticipated benefits...” In other words, an IRB can find that past actions can disqualify an investigator for a specific study, provided they appear to pose unreasonable risks to study subjects. For example, a conviction under a child abuse law might pose unreasonable risks for pediatric study subjects but not geriatric study subjects. The use of illegal drugs outside work might lead to their use at work. Bad judgment, unethical or immoral acts, or a lack of social consciousness outside work might suggest potential problems at work. However, environmental consciousness does not appear to map well to human subjects protection.

Most respondents in this survey would advise the FDA to disqualify an investigator based on actions outside clinical research, although there is disagreement on how serious a disqualifying action must be. If the FDA were to disqualify investigators from clinical research based on actions outside clinical research, due process would be required and take years. In addition, per the Supreme Court ruling in the FCC v. Fox Television Stations case, the FDA would have to specify the problematic actions: “Laws which regulate persons or entities must give fair notice of conduct that is forbidden or required.” Disqualifications would probably also require judgments of intent, degree and relevance to a specific study or type of study.

Should we want to move in this direction, one approach might be to modify the regulations to say that IRBs could consider an investigator’s actions outside clinical research when assessing risks to study subjects. However, that might take all the fun out of IRB membership.

Next Month’s Question

You are on a jury in a courtroom trial. The plaintiff is suing “everyone” for serious injuries received when she was hit by a car driven by the subject. The subject was in a clinical study of a medication that might cause drowsiness. Who, if anyone, is responsible for the plaintiff’s injuries? Read the full question and give us your answer at https://www.surveymonkey.com/r/5N32DHM.

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