When the LAR Is Also the Investigator

I once worked in a lab that conducted anti-aging research. The lab was operated by Dr. Smith, who also owned and operated an assisted living facility nearby.

Dr. Smith was intrigued by homeopathic remedies that he thought might slow the aging process and improve quality of life. His research centered on vitamin and nutritional supplements, topical creams and salves, exercise programs and so on. Laboratory personnel were constantly going to the assisted living facility and drawing blood, taking skin samples, measuring bone density and respiratory capacity and the like.

I began feeling uncomfortable when I noticed that some of our research participants, who had early senility or dementia and had little idea of what was going on, had their consent to research participation signed by Dr. Smith. When I asked him about this, he looked a bit anxious but told me that these individuals had signed over their power-of-attorney to him upon entering the facility, and that he was therefore allowed to make decisions for them, including research participation.

When we were informed that we were going to be visited by some representatives of a grant foundation that might fund our work, Dr. Smith explicitly told us to say that we knew nothing about how our various biological specimens were procured. He also told us to say that our current research was on the cusp of success even though none of our assays had indicated anything unique or exciting. He also made a point to remind all of us of the confidentiality and nondisclosure stipulations in our employment contracts, which sounded like a veiled threat should any of us discuss some of Smith's problematic practices with the funding team or any other outsiders.

We did not get the grant, and after a few months, I simply couldn't tolerate the situation any longer, and I left. Please comment.

Expert Opinion: When the LAR Is Also the PI

Before examining the stark conflict of interest that Dr. Smith is in, we might first discuss some issues bearing on Dr. Smith's (erroneous) understanding of his authority.

Although unusual, it is not unheard of for some individuals entering an assisted living facility to have the facility's administrator appointed as their surrogate for making certain decisions. Such persons would likely be without family or friends willing to assume a proxy or surrogacy role.[1] Of course, if they have judgmental capacity, they would have the right to make their own decisions; nevertheless, they could still appoint the facility administrator to make whatever decisions they would prefer not to (e.g., medical, financial, property, etc.). But if they are without such capacity, a court or some legally authorized entity would have to appoint the facility administrator as their proxy or durable power of attorney (DPA) in order for that appointment to have legal force.[2,3]

Now, assuming that Dr. Smith has been legally authorized as these persons' DPA, the above scenario tells us that he believes his DPA *also* entitles him to act as their "legally authorized representative" or LAR. The LAR is defined in the Code of Federal Regulations as:

"An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." (45 CFR 46.102 (c)) The LAR's primary responsibility, much like the surrogate's or proxy's in instances of clinical decision making, is to protect the rights and welfare of the potential research subject, especially by honestly representing the latter's preferences or presumed values about research participation.[2,3]

Dr. Smith's belief that his authority as DPA *automatically qualifies* him as a LAR is, at best, extremely questionable. The few states that have explicitly addressed this issue have, in fact, required court-appointed guardians to also obtain specific court authorization to make decisions on a ward's participation in a research project.[2] But very few, if any, states specifically allow what Dr. Smith is blithely assuming: namely, that a DPA *automatically confers authority* on that person to also serve as a LAR. The decision about the candidacy of surrogates, proxies or DPAs to serve as LARs is commonly left to the discretion of an institutional review board (IRB).[3]

And with that, we come to the heart of this scenario: It beggars belief that Dr. Smith has secured a responsible IRB to review his research and participant recruitment methods. Obviously, among those residents who lack sufficient judgmental capacity, no IRB would appoint Dr. Smith as a LAR until he could make a case to the IRB that he be recognized as such. But whether a resident had judgmental capacity or not, an IRB, court, or other judicial authority would likely insist that the PI of a project cannot serve as a LAR, just as a surgeon cannot do nonemergent surgeries without his patients' or their legally authorized representatives' consent. The United Kingdom's *Medicines and Human Use (Clinical Trials) Regulation 2004* explicitly disallows anyone serving as an LAR who is involved in the conduct of the trial.[4] To allow such would recall the embarrassing memories of research exploitation of vulnerable persons such as occurred in the United States at Willowbrook, the Jewish Chronic Disease Hospital in the Bronx, and the ones that were chronicled by Henry Beecher in his famous 1966 article "Ethics and Clinical Research."[5]

Very simply, Dr. Smith cannot possibly do justice to both roles of LAR and PI. As a LAR, he is tasked with protecting his charges from coercion, exploitation and manipulation. His job is to assess what his charges would voluntarily desire or what is in their best interests. He is obligated to question whether research participation might benefit his charges or whether the burdens or discomforts of participation outweigh any benefits his charges might experience. His primary role is very similar to the surrogate's in a clinical setting: to reflect, as much as possible, what the participant would want by way of participation or not, according to the participant's known or presumed preferences and beliefs.[2,3]

As the project's PI, however, Dr. Smith is ultimately "using" his research subjects just as any investigator does. Research participants are traditionally thought to serve as a means to an end—that end being the confirmation of a research hypothesis or securing generalizable knowledge.[6] Precisely because research participants are being used as instrumentalities in a project that might not benefit them in any way—indeed, their participation might eventuate in nothing but unpleasantness—their authentic, voluntary consent is crucial. But Dr. Smith is in no position to make that judgment for them in an honest and objective way, given his keen interest in enrolling as many participants as he can and generating data. That is why an IRB would surely disqualify him as a LAR.

Dr. Smith's role as the administrator of the facility only heightens worries about exploitation and coercion for any of the residents, whether they are judgmentally able or not. Just as prisoners might feel compelled to consent to research participation for fear that their warden might penalize them for refusing, it is easy to imagine that Smith's assisted living residents might fear some kind of reprisal—like dismissal from the living center or subsequently poor care-taking—if they would balk at participating in his research projects. Such a situation would qualify as coercion rather than manipulation or exploitation:[7] The residents do not wish to participate because of their anticipation of associated discomforts; but they also fear that their refusal will result in even more discomforts per their living conditions at the facility. Thus, they are worse off however they choose. Not only do they perceive no net benefit from participating, but their baseline welfare has been reduced: They can either suffer unpleasantries from participating in the research or suffer unpleasantries from refusing.

Some readers might object that, after all, the research interventions that Dr. Smith employs are only minimally risky, e.g., drawing blood, taking skin samples, measuring bone density, etc. But that objection misses the very keen, protective sensibility that IRBs and the Office for Human Research Protections impose on investigators. A familiar rule, for example, is that an investigator should only enroll participants without judgmental capacity in an investigation that is directly related to their incapacity.[3] If the same or similar research could be done on persons who have capacity, then it should be. As the 2009 OHRP Recommendations on Individuals with Impaired Decision Making in Research asserted: "Ease of recruitment or study cost should never alone justify the inclusion of individuals who lack consent capacity."[3,p.7]

Also, the Common Rule requires that "additional safeguards have been included in the study to protect the rights and welfare" of all subjects who are "likely to be vulnerable to coercion or undue influence." (45 CFR 46.111(b)). Thus, an IRB might appoint an additional party to perform oversight of the LAR him or herself. Indeed, one must always bear in mind that in many cases, even the best qualified persons to serve as a LAR will only have a dim idea of whether or not his or her charge would want to participate in *scientific research*.[3]

Does Dr. Smith even have a way of assessing his participants' capacity to make decisions? Could he show, for example, that he adjusts the degree of risk or discomfort of the research intervention in which residents are specifically participating (like weighing a resident versus drawing blood) to the resident's level of decision making? Would he be able to show that he honors anyone's dissent or refusal to participate in his study, regardless of their judgmental status? Or would he be hard pressed to point to anyone who has refused to participate?

Presumably, Dr. Smith was aware of all these eye-popping moral lapses in his censoring and threatening his staff per the upcoming site visit of a potential grantor. It is hard to imagine what kind of documentation Dr. Smith would have to show his compliance with ethical and legal guidelines for conducting research. Did he have an ethics advisory group available? Who were its members? How were they appointed? What entity served as his IRB? What quality measures could he point to that demonstrated his compliance with research protection guidelines, especially given his trio of staggeringly conflicted roles as facility administrator, PI, and LAR?

One hopes that the contributor of this dilemma didn't depart from her employment with Dr. Smith without also contacting legal authorities in the Department of Health and Human Services as well as the licensing entit(ies) of Dr. Smith's facility, so as to alert them to the charade posing as research that Dr. Smith was perpetrating.

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