Fumble

Anonymous Four

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and to my eye they seemed to remain unhappy with what had been discussed. They also made no declaration regarding their next move in the matter. Ultimately, though, the hospital administration determined that no one in the institution would try to force procurement.

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In the early 2000's I was a Community Member on the institutional review board (IRB) of a large medical institution. After five years with the committee, I understood my role and the value of our semi-monthly meetings. I was one of three Community Members on my committee—more nonscientists than most IRBs. I was proud of this. My institution was making efforts to do an excellent job and I felt they succeeded. I remember a particular clinical trial that greatly excited the ten physicians and researchers at the meeting. The study described the late stages of research about a vaccine with the potential to have important and positive effects on hundreds of thousands of persons in the United States and around the world. It was an example of research that would be of real and measurable value to a significant portion of society. But there was a problem: subject recruitment quotas were increasingly difficult to meet.

The primary reviewers were thorough in their evaluation and generous with their praise, but the recruitment problem—described modestly in the protocol—was not mentioned in the scientific discussion. The community member assigned to review the protocol (not me, in this instance) questioned the proposed, new methods of subject recruitment, but was reassured by other members that this kind of issue was not unusual. As the final vote was taken, my uneasiness grew like a balloon inside of me, filling me up and making it hard to breathe. The secretary of the committee was still calling for votes

as I nudged my fellow non-scientist to whisper, “Are you really okay with this recruitment strategy?” She whispered back, “Not really, but this seems pretty important. Maybe it’s not a big deal.”

I couldn’t stand it any longer. I interrupted the voting process, making a time-out “T” with my hands. “I hate to delay things, but your two Community Members are not comfortable. We understand the importance of this research, but it is *not* okay to ask and engage pathology labs to peruse patient test results to create lists of potential subjects to be contacted for enrollment in this study—without the prior consent of these patients for this kind of communication.”

There was an awkward silence. I think every person in the room was weighing my words to see if I had incorrectly described the proposed recruitment process. I had not. I imagine they each tried to articulate a reason why the proposed recruitment process was appropriate. They could not. Perhaps they hoped to find a compelling factor, something that could go “on the record”, that excused an inappropriate recruitment process for a greater social benefit. There was none. I could see these thoughts flit across the faces around me.

Into the quiet I said, “Yes, this is important. But it is clearly *not* okay to search patient files for abnormal lab results so they can be invited to this study. Even if they would want to be invited. Even if the greater good is significant. Even if this is the simplest way to find the right subjects.”

Disclaimer: my heart was pounding, my voice was trembling, and I was flushed red as a beet. I probably was not as coherent and concise as I remember, but I managed to convey the important point that I knew something was wrong, I knew what it was, and knew we couldn’t just bulldoze through the issue. In the conversation that followed, the entire committee dissected the recruitment strategy, agreed it was inappropriate and unanimously “deferred the decision” until acceptable modifications were made to the protocol. The letter to the primary investigator (PI) would describe the requested changes. I left the meeting feeling relieved and confident that IRB non-scientist input had been helpful

Well, the mud hit the fan. This was a well-funded, closely watched study. It was important to the institution and to the PI to keep the research moving forward. I should not have been surprised to see the PI at the very next meeting, ready to address the committee. Before we convened, the IRB chair pulled me and the other Community Member into a private office.

"It is important that the two of you speak up," he said. "This PI needs to see—and the record needs to reflect—that this protocol was deferred because the non-scientists were uncomfortable with the recruitment strategy. Your fellow IRB members agree with you, but you must speak up." We were a little startled by this extra attention, but appreciated the support and the instructions. We both agreed we would be candid with our comments.

It was a very uncomfortable meeting. The PI was livid. "Don't you understand the value of this research?" the investigator demanded. "Don't you see how many lives would be impacted by delay?"

I spoke up as promised. "No patient expects or wants their personal medical history to be searched for abnormal results that might qualify them for a study. If they did not give permission for this kind of access, then their records and lab reports should remain private." There was a familiar silence in the room. I could feel my words being weighed—and as before—there was no record-worthy response. My fellow Community Member spoke about her fear that this access would set a precedent that could invite future, more invasive intrusion. The PI spluttered some more, left the meeting and the committee once again, unanimously tabled the protocol.

This was my last official deliberation on this study. A few weeks later I learned that the PI had gone to the Dean, who had conferred with the chairs of all IRBs at the institution, and that an "appellate" IRB committee was formed. This temporary committee was comprised of physicians and scientists completely different than the original committee—with different Community Members as well. This new committee had reviewed the protocol, come up with a set of suggestions to modify the recruitment process, and spoken with the PI—who subsequently made changes to the protocol. The revised protocol

and the report from the "appellate" IRB came back to my committee, who considered the revisions and voted to approve the study. I was not present at this meeting nor informed that the study was under deliberation again. The revised recruitment strategy was not explained to me—I can only assume that appropriate standards to safeguard patient privacy were met. This sequence of events confused me. I felt that I had been "handled" and that the system has been tweaked to accommodate a special case, but I did not know how to follow-up on the matter and in any case, I got the sense that people didn't want to talk about it. With both dissatisfaction and relief, I let it go. I resigned my IRB service about 24 months later.

Twelve years have passed, and after filling larger, more public roles as a patient/subject advocate and studying bioethics and the regulations that govern human subject protection, I see this experience with new insight. First, I wonder why no one was willing to go "on the record" with discussion about the ethical implications of the recruitment practice. This fear of "official discussion being recorded" was crippling. I begin to think that many of the committee members did not know enough about research ethics and bioethics to feel comfortable framing their thoughts. Not that they had wrong thoughts, but perhaps they didn't have the vocabulary to express the right thoughts that they did have. Secondly, why wasn't a trained bioethicist brought in to facilitate a conversation? Maybe there *was* an argument for modifying the recruitment practice. Instead of turning the discourse into a hostile "us vs. them", it could have been a unifying interaction grounded on agreements about how respect for personal privacy might be balanced against greater social good. Thirdly, this dysfunctional communication led to bizarre, behind-the-scenes actions that only exacerbated the existing problem and opened the door, potentially, to new ones ("Appellate" IRB?!).

What is clear to me in hindsight, is *fear*: Community Members fearful of overstepping boundaries; physicians fearful of the institutional, professional and monetary repercussions of a critical vote; an IRB fearful of documented discussion about the grey areas of risks of one sort weighed against benefits of

a different sort. This committee of twelve years ago was comfortable dealing in the abstract, but when those principles became tangible, they sputtered and fumbled. They couldn't—or didn't know how to—ask for support or an ethical consultation, and as a Community Member, I certainly didn't know what to suggest. (Even today I am not sure if the harm of the proposed recruitment strategy measures up in any significant way against the—now—measured—in-a-span-of-years significant benefit of the research results—but I *do* know there should have been a conversation.) I learned two lessons: IRB members should speak up about their misgivings *and* free discussion with appropriate consultation should be encouraged. It is better to shed light on the issues and educate the committee than shroud concerns in mystery which creatinues dysfunctional behavior from which *nothing* is learned.

An Incautious Tale of Biomedical Ethics, Abortion Politics and Political Expediency

Mary Faith Marshall

Acknowledgment. Special thanks to the Charleston chapter of the NAACP.

On November 6, 1998, Medical University of South Carolina President James B. Edwards, DMD, wrote a letter to “MUSC Family and Friends” announcing his forthcoming retirement after 17 years at the helm. In his letter he quoted Warren Bennis (author of *Leaders on Leadership*):

In the postbeurocratic world, the laurel will go the leader who encourages healthy dissent, and values those followers brave enough to say “no.” The successful leader will have not the loudest voice, but the readiest ear. And his or her real genius may well be, not in personal achievement, but in unleashing other people’s talent.

Edwards closed: “While sometimes missing the mark, I and my administrative team have attempted to follow the above philosophy.”

Grammatical infelicities aside, this was absolute bushwa.

During my first month at MUSC (September, 1993) I learned about the *Interagency Policy on Management of Substance Abuse During Pregnancy* in a plenary session of a colleague’s ethic class. The presentation was made by the university’s general counsel, who stated, “we’ve written these women off . . . we want to save the babies.” There was laughter, but no dissent from the students or faculty filling the auditorium. The policy had, by then, resulted in the arrest of 39 MUSC obstetrics patients—“these women”—who used illegal drugs while pregnant and who had somehow “failed” treatment for substance abuse. The policy conditioned freedom from arrest on compliance with mandatory prenatal and substance abuse treatment. Of the patients arrested, all but one were African-American. The program was a joint venture between the obstetrics department of MUSC, the local prosecutor, and the Charleston police department.

In October, 1993, *Ferguson et al vs the City of Charleston et al* was filed in federal district court on behalf of 11 women arrested under the *Interagency Policy*. It was, unfortunately, often referred to by the defendants and the media as “the Cocaine Baby trial.” The case ultimately made its way to the U.S. Supreme Court.

An early sign of things to come: Edwards had asked me my position on abortion during an initial meet and greet shortly after I arrived at MUSC. Abortion politics were, after all, what the case of *Ferguson et al v the City of Charleston et al* was all about . . . making the fetus a person under auspices of the state’s child protection statute. South Carolina was the first state to do so.

It was basically a fuck you—Edwards’ refusal in 1998 to put my promotion before the Board of Trustees because, as he stated in a letter to me, of my “testimony in the ‘Cocaine Baby’ trial.” He knew it couldn’t hold, so did the university’s general counsel—I’d been subpoenaed to testify in federal district court. My promotion had made its way through the university to the penultimate step. I’d received a congratulatory letter from Ian Taylor, my department chairman. But it took over a year, \$19K