Editorial

Requiem for Research

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As a clinical researcher, there is no situation more frustrating than to discover that by the time your study protocol has been approved, the study has already been filled and closed by the sponsor. Welcome to the current world of clinical pharmaceutical research in academic dermatology. In this system, you submit a protocol, fill out regulatory documents, attend an investigator meeting, and, after many hours of work, never enroll a single patient. In reality, it does not always proceed in this fashion, but it certainly seems that way.

Over the past few years, there has been an ever increasing shift in the paradigm for clinical research in our field. Study sponsors, frustrated by the slow workings of hospital institutional review boards (IRBs), have begun to favor private research groups that are able to utilize central IRBs. In addition, these private research groups offer a cost-effective alternative, in which study sponsors do not have to pay the prohibitive overheads charged by academic centers. And let's not forget *HIPAA*, the most feared 5 letters for clinical researchers since *death*.

Recently, I have had several interactions with study sponsors that illustrate this trend. A colleague recommended our center for a wound care study seeking additional sites. The interaction was going well until I mentioned that the potential study site was an academic center. I was subsequently informed that, given their deadlines and urgent need for data, the sponsor could not afford the potential delays by using us. In another instance, I received a fax regarding a psoriasis study and contacted the inquiring clinical research organization. During the conversation, I was told that they had met their quota of academic centers. They informed me, however, that if I had an outside private office, I would certainly be welcome to participate in the study at that location.

There is an irony in this. I entered academic medicine, in part, so that I could perform research, and now that is becoming a distinct disadvantage. The private groups offer many advantages; they are fast, cost-effective, and do an outstanding job. Many of the researchers in private practice are those who have previously left academia because of the obstacles and frustrations I have noted. Therefore, it is unfortunate on 2 levels: academia has lost much of the research, and many of the talented researchers and teachers have followed it out the door.

Therefore, I fear that we are most likely witnessing the final days of academic clinical research in dermatology, unless there is reform in the system. Unfortunately, there are no simple solutions. One necessary step is for hospital IRBs to become more efficient. Without compromising patient safety, these bodies should strive to expedite the review process and streamline administrative processes. These changes would aid academic centers in successfully competing for study participation. Second, research sponsors should commit to having a fair proportion of their sites dedicated to academic centers, despite the potential for delay and increased cost. With the best of both worlds represented, dermatologists will continue to achieve excellence in our research endeavors.