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I am in receipt of your document dated February 12, 2008. I feel that you need to be aware of the factors which came into play to cause the situation which occurred. As per your request, I will conclude with my plans and interventions to address the identified concerns for future potential involvement in research protocols.

I am a physician who has practiced Chronic Wound Management as my primary practice area for over 10 years. My practice has been located in medically underserved areas of Indiana.. I have always aggressively pursued available options for improving the care of my patients, especially in light of the chronic and/or recurrent nature of their illnesses. When I realized that participation in research protocols could avail my patients of otherwise unavailable treatments, I enthusiastically pursued the training and opportunities. I readily acknowledge signing 1572's for all protocols and fully understand the implications of this document.

Identifying, hiring and training qualified personnel is always problematic and more so in an economically deprived area such as mid-southern Indiana. Nonetheless, I tried to identify personnel that had the potential to learn the guidelines and implement them per the accepted standards. Research sponsors, monitors, and other pertinent entities were advised of the status of research education of my site and staff via requested information. Unfortunately, the transient nature of the population in this area led to staff changes, all too often in mid protocol.

In early studies at my facility, I had several employees who started working at research coordinators in conjunction with oversight by the monitors and sponsors. I tried to have at least two of my staff involved in the protocols recognizing that the economics of the area and the penchant for employees to seek other employment without notification existed. In [redacted], I identified a nurse who professed limited research experience, but demonstrated maturity and professed an interest in being a research coordinator. She initially showed maturity, enthusiasm, intelligence and a desire to provide great care to patients. I did my due diligence and did not identify any suspicious background findings. Several studies were commenced and she seemed to be maintaining appropriate records and following the protocol. However, I soon discovered that concerning communications from sponsors were increasing with respect to erroneous, incomplete and inadequate data, information and responses to questions. Initially, I discussed my concerns with my RC who assured me that these were being addressed and there was no reason for concern. In medical practice, the day to day activities are relegated to the appropriate staff with the physician attending to issues requiring their level of expertise. The assumption and expectation that the RC was attending appropriately to her specified duties is not an unreasonable expectation. To the best of my knowledge, I saw some limited improvements and felt that the problem had been addressed and resolution and improvement was underway. After subsequent, extensive discussion with sponsors and having requested monitoring visits, I began a more intensive overview and discovered many errors in different areas of the research. The monitors assured me

they would do a more intensive scrutiny as well and also maintain better contact with the RC to assure better responses. Unfortunately, the RC began to have [redacted] problems and I discovered that her solo research "paperwork" time was being spent [redacted] and that her adherence to research protocols and attendance to details of the protocols had been markedly compromised. Additionally, her [redacted] had a detrimental effect on my office staff resulting in the loss of one integral member. I [redacted] and as I was in mid protocol, felt that the ongoing research could be continued. With the support of the respective sponsors, I elected to try to find another RC to complete the studies. I informed the sponsors of my actions throughout this situation and after identifying another candidate who I felt would be a suitable RC, I requested assistance from all sponsors at that time to provide training and education. She also was given the guidelines to review with respect to the conduction of research and ethics which I personally reviewed with her. This RC was several months into the protocols and seemed to be making inroads when [redacted] At this point, I discussed the status of the ongoing protocols with the sponsors and voluntarily elected to [redacted] them.

In late 2004 and into 2005, I had a significant personal family crisis which took a significant toll on my personal and professional well being. I had a Physicians Assistant and several physicians as sub-investigators on several of the ongoing protocols. Unfortunately, on many of the occasions when I was unable to fully perform my duties as the PI, there were occasions when my back up was unable or unwilling to provide the services they had agreed to. This resulted in several occasions when timing of events was off protocol and other issues related to timing or data collection. I attempted to rectify these situations when possible realizing that there would be protocol violations. My goal was to try to minimize potential harm while still attempting to perform the protocol in as loyal a manner as possible. Additionally, I discovered after the fact that the aforementioned RC had [redacted] with several of my sub investigators and gave them erroneous information regarding protocol performance. While monitoring visits identified numerous problems, corrective action which was promised by the RC never took place in many instances which was not discovered until follow up visits after [redacted] Her successor at the RC was simply unable to decipher many of these issues even with monitor assistance [redacted].

I have had considerable opportunity to review my performance on these protocols as well as discuss corrective action with the monitors, sponsors and other principal investigators involved in the same protocols. I recognize that many of these issues were unavoidable even under the best circumstances however; I acknowledge that there are actions I need to take to assure that future protocol participation is done in a more acceptable fashion.

- At the present time, I am not involved in any active protocols nor do I have any plans or expectations to resume the role as PI or Sub investigator in the foreseeable future. The termination of the last of any "active" research protocols occurred in late 2007 after [redacted] my RC. I do not currently have any plans or arrangements to resume participation in human subject research protocols.

- I am in the process of relocating my primary wound care practice to Indianapolis, Indiana. This assures me of a larger pool of potential employees who have familiarity with research protocols in the unlikely event that I consider resumption of human subject research

- I have identified (though no contact has been made with) research departments in several Indianapolis medical and scientific facilities from which I would obtain training, and assistance in the performance of research protocols.

- Whereas my previous situation was as a solo Principle Investigator with no hospital affiliation and hence difficulty identifying sub investigators, I have joined the medical staff of a teaching hospital in Indianapolis. This will provide me a pool of support staff and sub investigators for any future research opportunities.

- This new position will also allow me to avail myself of better investigative and evaluative processes and procedures to better weed out undesirable employees and improve the odds of having employees better suited for research

- I have identified courses pertaining to performance of research protocols and related issues and recognize that furthering my education in this area is needed should I resume protocol participation.

- I will assure that all personnel involved in the protocol receive appropriate training and document this training in all pertinent aspects of human subject research.

- Regardless of the credentials and training of my RC, I will endeavor to provide more oversight of the day to day activities regarding the protocols.

- For any future protocol participation, I understand the need to have more layers of oversight to assure that protocol adherence is performed according to standards. This means that the actions of the RC will be more closely monitored by me, that there will be more requested oversight and feedback from the monitors and sponsors and more "spot checks" by appropriate personnel.

In closing, I understand the seriousness of the participation and performance of human subject research protocols. I acknowledge the findings of the FDA evaluation of protocols performed under my auspices and understand the implications. It is my current plan to not continue participation in human subject or other research protocols in the foreseeable future. In the unlikely event that an appropriate opportunity to do so presents itself, I would endeavor to initiate and follow through with the aforementioned actions and activities and any others as deemed appropriate by the FDA, Institutional review boards, the sponsors, monitors and any other authoritative bodies.

Yours

/s/

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cc:
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