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TITLE: Randomized Trial of an Environmental Medicine Approach to Gulf War Veterans' Illness

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14. ABSTRACT Since we have been working for a full year to get institutional Review Board Approval for this project and have not yet succeeded, we have learned the extreme difficulty in getting IRB approval for a safe, relatively noninvasive therapy. We have also learned that there are multiple layers of review, and that after each review there are extensive clarifications, revisions, and additional details requested.						
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INTRODUCTION:

The purpose of the research is to study the efficacy of an environmental medicine approach to Gulf War Veterans' Illnesses. The hypothesis to be tested is these illnesses result from a maladaptation to the chemical environment to which we are all exposed, as described by Selye and Randolph. The approach is to house ill veterans in an environmental control unit, to start them on a rotation diet after a brief diet, and to monitor them for symptoms from exposures to foods and airborne chemicals. Adjuncts include allergy testing using the provocative-neutralization technique, vitamin supplements, exercise, and sauna-detoxification.

BODY:

We are still working on the first task, which is to obtain Institutional Review Board approval for the study. Efforts to obtain Institutional Review Board (IRB) approval for this grant are still under way. After the award was made, the DOD IRB reviewed the IRB and requested revisions. After a second review, we were instructed to seek approval from the East Carolina University (ECU) IRB before further review by DOD. The ECU IRB reviewed the protocol in January 2008 and requested changes. These were made, and the ECU IRB approved the protocol in March 2008. The ECU attorney objected to the ECU IRB acting as IRB for the Environmental Health Center – Dallas (EHCD) even though the proper affiliation agreement had been signed, the ECU IRB was in agreement, and the researchers at Dallas had taken the necessary training. Hence, the EHCD had to become certified to have their own IRB, which required extensive paper work and more delays. The EHCD IRB met in May 2008 and approved the protocol. The protocol was then forwarded to the DOD IRB for final review. The DOD IRB required until September 2008 for their third review of the protocol. In September 2008 we received a 27 page document requesting extensive changes. To meet the multiple objections, the entire protocol has to be redesigned. We hope to have this completed in the next week or so. The DOD IRB has said they will perform another review after the changes are made. How long this will take is below our control. The protocol is an environmental medicine approach to Gulf War Veterans illnesses. This approach involves housing in unpolluted air, a brief fast followed by a rotation diet, exercise and sauna, vitamin supplements, and allergy testing. This is a safe approach that has been used on tens of thousands of patients

over the last fifty years. We have faith that the protocol will be approved soon and we can begin the research.

KEY RESEARCH ACCOMPLISHMENTS:

There are no key research accomplishments because we cannot begin the research until we obtain IRB approval to start the research.

REPORTABLE OUTCOMES:

None at this time.

CONCLUSION:

It is very difficult to get IRB approval for this project, requiring multiple levels of review, each of which takes months, and each of which requires extensive clarifications, revisions, and further review by all three IRBs.