# VCU Memo

Virginia Commonwealth University

Office of Research Subjects Protection
BioTechnology Research Park
BioTech One, 800 E. Leigh Street, #114
P.O. Box 980568
Richmond, Virginia 23298-0568
(804) 828-0868
(804) 827-1448 (fax)

DATE: January 9, 2012

TO: Spencer E. Harpe, PharmD, PhD, MPH
Pharmacotherapy and Outcome Science
Box 980533

FROM: Lloyd H. Byrd, MS LHB/DA
Vice-Chairperson, VCU IRB Panel B
Box 980568

RE: **VCU IRB #: HM14033**
**Title: Factors Influencing Pharmacists' Decision to Report of Adverse Events Related to Dietary Supplements**

On January 6, 2012 the following research study ***qualified for exemption*** according to 45 CFR 46.101(b) Category 2. This determination includes the following items reviewed by this Panel:

**RESEARCH APPLICATION/PROPOSAL: NONE**

**PROTOCOL:** Factors Influencing Pharmacists' Decision to Report of Adverse Events Related to Dietary Supplements, version1-9/30/11, received 11/2/11

**CONSENT/ASSENT:**

- Because the project is exempt from federal regulations, the procedures described in § 46.116 (Consent) and 46.117 (Documentation of Consent) are not applicable to your research study. Nevertheless, the Common Law of the Commonwealth of Virginia, as well as the canons of sound ethics require you to inform potential subjects of foreseeable risks and possible benefits (if any) associated with participation in your research study. Therefore potential subjects should be informed of foreseeable risks and possible benefits of participation in your research study. They should also be informed that they may refuse to participate in your research and they should understand that they might withdraw at any time without penalty. They should then be invited to provide verbal consent.
- This process of informed decision-making should be documented along with other information associated with the study.

**ADDITIONAL DOCUMENTS:**

- Participant Recruitment E-Mail, version 1-10/31/11, received 11/2/11
- Thank You/Reminder Email, version 1-10/31/11, received 11/2/11
- Second Participant Thank You/Reminder, Email, version 1-10/31/11, received 11/2/11
- Final Thank You Email, version 1-10/31/11, received 11/2/11

The Primary Reviewer assigned to your research study is Richard Gayle, EdD. If you have any questions, please contact Dr. Gayle at rgayle@vcu.edu and 827-9337; or you may contact Donna Gross, IRB Coordinator, VCU Office of Research Subjects Protection, at dsgross@vcu.edu or 827-2261.

**Attachment – Conditions of Approval (PLEASE NOTE RECENT CHANGES TO #3)**

## *Conditions of Approval:*

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must *(as applicable):*

1. Conduct the research as described in and required by the Protocol.

2. Provide non-English speaking patients with a translation of the approved Consent Form in the research participant's first language. The Panel must approve the translation.

3. The following changes to the protocol **must be** submitted to the IRB panel for review and approval before the changes are instituted. Changes that do not meet these criteria do not have to be submitted to the IRB. If there is a question about whether a change must be sent to the IRB please call the ORSP for clarification.

   **THESE CHANGES MUST BE SUBMITTED:**
   a) Change in principal investigator
   b) Any change that increases the risk to the participant
   c) Addition of children, wards of the state, or prisoner participants
   d) Changes in survey or interview questions (addition or deletion of questions or wording) that change the level of risk or adds questions related to sexual activity, abuse, past or present illicit drug use, illegal activities, questions reasonably expected to provoke psychological anxiety, or would make participants vulnerable, or subject them to financial, psychological or medical risk
   e) Changes that change the category of exemption or add additional exemption categories
   f) Changes that add procedures or activities not covered by the exempt category(ies) under which the study was originally determined to be exempt
   g) Changes requiring additional participant identifiers that could impact the exempt category or determination
   h) Change in inclusion dates for retrospective record reviews if the new date is after the original approval date for the exempt study. (ex: The approval date for the study is 9/24/10 and the original inclusion dates were 01/01/08-06/30/10. This could be changed to 01/01/06 to 09/24/10 but not to end on 09/25/10 or later. )
   i) Addition of a new recruitment strategy
   j) Increase in the planned compensation to participants

4. Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.

5. Report Unanticipated Problems (UPs), following the VCU IRB requirements and timelines detailed in VCU IRB WPP VIII-7).

6. Promptly report and/or respond to all inquiries by the VCU IRB concerning the conduct of the approved research when so requested.

7. The VCU IRBs operate under the regulatory authorities as described within:
   a) U.S. Department of Health and Human Services Title 45 CFR 46, Subparts A, B, C, and D (for all research, regardless of source of funding) and related guidance documents.
   b) U.S. Food and Drug Administration Chapter I of Title 21 CFR 50 and 56 (for FDA regulated research only) and related guidance documents.
   c) Commonwealth of Virginia Code of Virginia 32.1 Chapter 5.1 Human Research (for all research).

## APPENDIX D: Thank You/Reminder E-Mail Template

### 1. First participant "Thank You/Reminder" e-mail

Dear participant,

About one week ago, you should have received from me an e-mail that contained a link to an online survey to help me complete my dissertation research project. As a brief reminder, my dissertation project is focused on examining the factors that influence whether pharmacists report adverse events associated with the use of dietary supplements. Identifying these factors may help in developing educational programs to improve the awareness of pharmacists and other healthcare professionals about dietary supplements and the need for systematic safety surveillance.

If you have already responded to the survey, I sincerely thank you for your participation. You can disregard this e-mail. If you have not yet completed the survey, I would greatly appreciate your taking the time (about 15 minutes) to complete the survey by following the link below. All of your responses will be anonymous, and your participation is completely voluntary.
http://vcupharmacy.us2.qualtrics.com/SE/?SID=SV_bloYvnmMf3g4tPS

Your participation would greatly help me complete my dissertation project. If you have any questions, please feel free to e-mail me or my advisor, Dr. Spencer Harpe (seharpe@vcu.edu).

Thank you in advance for helping me with my research project.

Best,

Ali Al-hammad


## APPENDIX C: Participant Recruitment E-Mail Template

Dear participant,

My name is Ali Al-hammad. Currently, I am a PhD student at the VCU School of Pharmacy where I am focusing on drug safety issues. One of my particular interests is in the safe use of complementary and alternative therapies, such as natural products and dietary supplements. My dissertation project is focused on examining the factors that influence whether pharmacists report adverse events associated with the use of dietary supplements. Identifying these factors may help in developing educational programs to improve the awareness of pharmacists and other healthcare professionals about dietary supplements and the need for systematic safety surveillance.

I have chosen to use pharmacists who have served as preceptors for VCU pharmacy students. Below is a link to an online survey. It should take about 15 minutes to complete. All of your responses will be anonymous, and your participation is completely voluntary. More information about the project and the survey itself can be found by following the link.
http://vcupharmacy.us2.qualtrics.com/SE/?SID=SV_bloYvnmMf3q4tPS

Your participation would greatly help me complete my dissertation project. If you have any questions, please feel free to e-mail me or my advisor, Dr. Spencer Harpe (seharpe@vcu.edu).

Thank you in advance for helping me with my research project.

Best,

Ali Al-hammad

APPROVED
11/1/2016


**2. Second participant "Thank You/Reminder" e-mail**

Dear participant,

About two weeks ago, you should have received from me an e-mail that contained a link to an online survey to help me complete my dissertation research project. As a brief reminder, my dissertation project is focused on examining the factors that influence whether pharmacists report adverse events associated with the use of dietary supplements. Identifying these factors may help in developing educational programs to improve the awareness of pharmacists and other healthcare professionals about dietary supplements and the need for systematic safety surveillance.

If you have already responded to the survey, I sincerely thank you for your participation. You can disregard this e-mail. If you have not yet completed the survey, I would greatly appreciate your taking the time (about 15 minutes) to complete the survey by following the link below. All of your responses will be anonymous, and your participation is completely voluntary.
http://vcupharmacy.us2.qualtrics.com/SE/?SID=SV_bloYvnmMf3q4tPS

Your participation would greatly help me complete my dissertation project. If you have any questions, please feel free to e-mail me or my advisor, Dr. Spencer Harpe (seharpe@vcu.edu).

Thank you in advance for helping me with my research project.

Best,

Ali Al-hammad

APPROVED
1/6/12 | 16 | 26

### 3. Final "Thank You" e-mail

Dear participant,

I sincerely thank you for assisting me with my dissertation research. Your participation would greatly help me complete my dissertation project.

If you have any questions, please feel free to e-mail me or my advisor, Dr. Spencer Harpe (seharpe@vcu.edu).

All of your responses will be anonymous, and your participation is completely voluntary.

Best,

Ali Al-hammad