INFORMED CONSENT

TITLE: **DIETARY INTAKE AND BEHAVIOR IN COMPETITIVE WOMEN BODYBUILDERS**

PRINCIPAL INVESTIGATOR: Dr. Jerry W. Lee, PhD

CO-INVESTIGATOR: John E. Haubenstricker, MS, RD, CSSD, EP-C

WHY IS THIS STUDY BEING DONE?

The purpose of the study is two-fold: 1) to examine of the dietary intake, dietary supplement intake, and diet quality characteristics of competitive women bodybuilders; and 2) to understand the factors that lead to dietary protein intake and dietary supplement use. You are invited to be in this study because you are competitive women bodybuilder who is either currently competing, plans to compete in the next year, or has competed in the past year in one of the physique categories (i.e., bodybuilding, bikini, figure, fitness, physique, or wellness). Approximately, 228 individuals will participate in this study throughout the United States. Your participation in this study may last up to three weeks.

HOW WILL I BE INVOLVED?

Participation in this study involves completing four, non-consecutive dietary recalls and a questionnaire about factors related to dietary protein and dietary supplement intake, your personal characteristics, general health, competition details, diet, physical activity, and supplement use. The four, non-consecutive dietary recalls need to be completed no more than one week after completion of the questionnaire. The completion of the questionnaire and four dietary recalls will take approximately 2-3 hours. The purpose of completing the questionnaire and four dietary recalls will be to describe the dietary intake, dietary supplement intake, and diet quality in competitive women bodybuilders. In addition, the study will help to identify/provide insight into the factors associated with dietary protein intake and dietary supplement use in competitive women bodybuilders.

WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MIGHT HAVE?

This study poses no greater risk to you than what you routinely encounter in day-to-day life. Participating in this study involve several risks, which include a possible breach of confidentiality and privacy, and the possibility of disclosing the use of illegal substances. All records and research materials that could identify you will be held confidential. Information identifying you will only be available to the study personnel. Only the co-investigator listed on the front page will lead the administration of the questionnaire and four, non-consecutive dietary recalls. Data will be held by the investigator in a password protected file; while the co-investigator will save the data onto a password protected and encrypted external hard drive. Once the data has been checked and cleared of errors, all identifiers connecting you to the data will be

destroyed. Once the identifiers have been destroyed, no participant can be identified in any published document resulting from this study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it and such a request must occur before the investigators have destroyed all identifiers in the files.

WILL THERE BE ANY BENEFIT TO ME OR OTHERS?

There may be no direct benefit from participating in this study. Your participation, however, will help practitioners to better understand the factors associated with dietary protein intake and dietary supplement use as well as the relevant athlete-specific characteristics and diet-related and dietary supplement characteristics in competitive women bodybuilders. Upon completion of each dietary recall, you will have the option to obtain a nutrition report to compare your intake to U.S. dietary guidance and nutrient requirements. You may gain a better understanding of your dietary intake and dietary supplement intake and potential areas for improvement. We do not guarantee such benefits.

WHAT ARE MY RIGHTS AS A SUBJECT?

Your participation in this study is entirely voluntary. You may refuse to participate or withdraw once the study has started. Your decision whether or not to participate or terminate at any time will not affect your future standing with the researchers. You do not give up any legal rights by participating in this study. If at any time you feel uncomfortable, you may refuse to answer questions.

WHAT COSTS ARE INVOLVED?

There is no cost to you for participating in this study.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

For lump sum, you will be paid $100 when you complete this study.

WHO DO I CALL IF I HAVE QUESTIONS?

Call 909-558-4647 or e-mail patientrelations@llu.edu for information and assistance with complaints or concerns about your rights in this study. For questions about the study, itself, please email John Haubenstricker at jhaubenstricker@llu.edu.

SUBJECT'S STATEMENT OF CONSENT

- I have read the contents of the consent form and have emailed John Haubenstricker at jhaubenstricker@llu.edu if I have questions about the study.
- My questions concerning this study have been answered to my satisfaction.
- Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.
- I hereby give voluntary consent to participate in this study.

I understand I will be given a copy of this consent form after signing it.

Signature of Subject	Printed Name of Subject
Date	

INVESTIGATOR'S STATEMENT

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

Signature of Investigator	Printed Name of Investigator
Date	