Sample Research Protocol

The pages that follow contain a sample research protocol, including and informed consent document and other appendices.

This document is provided as guidance to investigators for the preparation of protocols and consent documents.

It cannot be slavishly followed as all protocols are different and not all possible variations can be captured in a single sample.

Questions may be addressed to:

Irv Freeman, Ph.D., J.D.
Chair of the LECOM Institutional Review Board
Phone: (724) 552-2870, or
Email: ifreeman@lecom.edu.

Request for Approval of Human Subjects Research

Title: *Demographic and Other Factors Affecting Incidence of Singultus Among the Hot-and-Sour Soup Eating Population*

Principal Investigator:

G. I. Specialist, D.O., MPH
Clinical Professor of Internal Medicine
Lake Erie College of Osteopathic Medicine

Dr. Specialist is board certified in internal medicine with subspecialty certification in gastroenterology by both the American Osteopathic Board of Internal Medicine and the American Board of Internal Medicine and has five years of practice experience since completion of her fellowship. Via her MPH program, she has substantial training in research design and statistical analysis. She is the sole author or a co-author of four peer-reviewed papers and of at least seventeen published abstracts or poster presentations and has served as Principal Investigator of three prior studies involving human subjects. She most recently completed CITI human subjects protection training for Principal Investigators within the past month (documentation attached).

Research Question:

The primary question of this research is to establish the incidence of singultus following the ingestion of Hot and Sour Soup by regular consumers of Chinese Food (as prepared in Chinese restaurants in the United States). An additional research question is whether there are differences in the incidence based on demographic factors (i.e. age, race, gender) and/or comorbidity factors.

Brief Review of the Literature:

Since the publication in 1898 of E. E. Kellogg's monumental and pathbreaking "Science in the Kitchen: A Scientific Treatise on Food Substances and Their Dietetic Properties, Together with Practical Explanation of the Principles of Healthful Cookery, and a Large Number of Original Palatable, and Wholesome Recipes," there is a huge literature concerning the impact of various foods on overall health and on specific disease states. While there is general information published on the nutritional characteristics of Hot and Sour Soup (see, for example, Jessica Bruso, Nutritional Facts for Hot & Sour Soup, at http://www.livestrong.com/article/398535-nutritional-facts-for-hot-sour-soup/) and on its potential health benefits (see, for example, M. Eileen Brown, Soupalooza: Hot and Sour Soup Cures What Ails You., at http://www.dailyherald.com/article/20130225/entlife/702259755/), there does not

appear to be any published prior research on the anecdotally observed phenomenon of hiccoughs following consumption of hot and sour soup. This study will fill that gap in the scientific literature.

Methodology:

Subject Recruitment. Subjects will be recruited from among the customers who order Hot and Sour Soup at five cooperating Chinese restaurants (of the "Chinese Buffet" variety). The restaurants will be provided with copies of the recruitment leaflet (copy attached) and will be asked to provide a copy of the leaflet to each customer who orders Hot and Sour Soup. The restaurant staff's role will be solely to distribute the leaflets, they will not answer questions about the research or participate in the informed consent process.

Prospective subjects will be asked to contact the investigator by telephone. They will be provided with a brief verbal overview of the study and, if interested will then be verbally screened for exclusion factors (known dietary allergies to Hot and Sour Soup ingredients, diabetes, current treatment for GERD, history of gastric ulcers, status as a minor). No written record will be made or maintained of the screening. If eligible, the prospective subject will be sent a copy of the informed consent document (copy attached). The PI will then schedule a telephone call for after the subject has had an opportunity to read the consent form and will answer any questions at that time. Then, if the prospective subject agrees to participate, he or she will be asked to sign the consent form and either to send it to the investigator or to bring it to the first experimental session.

Experimental Sessions. Experimental sessions will occur on five consecutive Wednesday evenings, one at each of the five cooperating Chinese restaurants. Subjects will each be provided with a pint of that restaurant's Hot and Sour Soup and asked to consume the entire portion in one sitting. The subjects will be under observation during consumption and for a period of fifteen minutes post-consumption. Any episodes of hiccoughs during the period of observation will be noted. Subjects who are still hiccoughing at the end of the initial observation period will be requested to remain for additional observation. Following the observation, subjects will be offered a complimentary meal at the buffet. If subjects are still hiccoughing at the restaurants closing time, the PI will contact them by phone twice on each of the next two days (or until the hiccoughing resolves). If hiccoughing does not resolve within 48 hours (the common criterion for "persistent singultus"), the subject will be referred for medical treatment and will be removed from the study.

Other Data Collection. At the first experimental session, subjects will complete a questionnaire collecting demographic data and data on their prior medical history. The form utilized will be a standard, commercially available form

used in primary care physicians' offices. Prior to the first intervention (i.e. the first bowl of Hot and Sour Soup) the history form will be reviewed by the PI for exclusion criteria and additional subjects may be excluded at this time (subjects excluded at the restaurant will be provided with the complimentary buffet). Subjects will also be asked for the contact information of their primary care physicians, if any. With appropriate HIPAA authorization embedded in the Consent Form, the PCPs will be asked to disclose any prior incidents of singultus.

Risks. Potential physical risks of participating in the study include transient burning sensation in the lips, mouth, and esophagus from the potentially spicy nature of the soup, aggravation of pre-existing G.I. conditions, allergic reaction, weight gain, elevation of blood glucose. Procedures to minimize risk include the screening for exclusion criteria and the exclusion of prospective subjects reporting those criteria; the presence of the PI, a board-certified internist, at all experimental sessions; and the up to two-day follow-up as described above. In addition, any subjects who are observed to have an adverse reaction or who later report an adverse reaction will be discharged from the study before participating in additional experimental sessions.

There is also a potential risk of breach of confidentiality. To minimize this risk, each subject will be assigned a sequential identifying number. This number, rather than the name, will be placed onto the data collection form at each experimental session and onto the questionnaire. The subject will be provided a card with the number and will be asked to bring the card to each session. The PI will maintain a separate list linking identities to names, but this list will be stored in a separate location from other study data and will remain in a locked cabinet except when in use. The linking list will be destroyed when data collection is complete. If PHI is obtained from the subject's PCP, response (i.e. either Yes or No on prior incidents of singultus) will be recorded onto the subject's questionnaire and the report received from the PCP will be destroyed.

Benefits. No direct benefits to the particular subjects are anticipated. The benefit to society is the contribution to knowledge that will be obtained by either documenting or debunking the anecdotal association between Hot and Sour Soup and hiccoughs and, if an association is found, by the subsequent analysis of the demographic differences or differences based on medical history.

Analysis. The overall incidence of hiccoughs and the incidence at each of the participating restaurants will be calculated. Demographic factors and medical history factors will be tested statistically to determine if the incidence varies based on those factors.

Consent Process. The consent process was described above in the "subject recruitment" section. The investigator also requests that the IRB approve partial

waiver of the informed consent requirement, specifically that the element of informed consent that involves disclosing the purpose of the research be partially waived such that the consent process describes the purpose as to determine the impact of hot and sour soup on physiological processes in general, rather than specifically identifying hiccoughing. It is believed that knowledge on the subjects' part of the focus on hiccoughing could influence the occurrence of that outcome.. The criteria for approval of the partial waiver are addressed below:

1. The research involves no more than minimal risk to the subjects.

According to the Federal government, "A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." The risk-producing intervention of this study is the consumption of hot and sour soup. The subjects are limited to individuals who have been observed ordering hot and sour soup in their ordinary daily lives. Thus, the risk is exactly the same as the risk that they ordinarily assume themselves when not involved in research.

2. The waiver will not adversely affect the rights and welfare of the subjects.

The subjects will still receive a complete explanation of the experimental intervention and of all other data collection. The subjects will also be generally aware that the purpose is to assess any physiological effects of consuming the soup. They will simply not know the specific effect that is of interest to the investigator.

3. The research could not practicably be carried out without the waiver or alternation.

Psychological factors such as excitement and emotional stress have been cited as a cause of hiccoughs (see, for example, http://www.mayoclinic.org/diseases-conditions/hiccups/basics/causes/con-20031471). To control for the impact of psychological factors, it is requested that subjects be blinded to the specific interest in hiccoughs lest hiccoughs induced by the stress of desire-to-please not confound the results.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Following the fifth experimental session (or earlier if a subject withdraws or is discharged), the subject will be provided with a written explanation (copy attached) of the true purpose of the study and with an explanation of the reason for the deception.

Hot & Sour Soup Research Study

Dr. G.I. Specialist is conducting research on the physiological impact of eating Hot and Sour Soup.

Participants will provide information about themselves, will eat five large bowls of Hot and Sour Soup (one each on five different days), and will be observed for at least fifteen minutes after each bowl. Participants will receive free buffet dinner each time.

If interested, call Dr. Specialist at 800-555-5555.

Consent to Participate as a Subject in a Research Study

Physiologic Effects of Eating Hot & Sour Soup

Introduction

You are being invited to participate in a research study. The purpose of the research is to determine whether eating hot & sour soup has any immediate short-term effects on the human body that may be observed immediately following eating the soup. You are being invited to participate because you were observed ordering hot & sour soup in one of the participating restaurants. It is estimated that approximately 50 people will participate in the research.

Voluntary Participation

Whether or not you wish to participate is entirely up to you. Participation is voluntary and refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled. Similarly, if you agree to participate, you may withdraw or discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

What Your Participation Will Involve

If you agree to participate in this study, you will participate in five experimental sessions. The sessions will occur on five consecutive Wednesday evenings, one at each of five cooperating restaurants. So, the overall duration of your participation will be five weeks. At the first session, you will be asked to complete a brief form providing demographic information (i.e. gender, race, age) and medical history information. The form will be similar to medical history forms that you have probably completed at your doctor's office. The Researcher anticipates that completion of the form will take most participants 20 minutes or less.

After the completion of the form at the first visit, and immediately upon arrival at the other four visits, you will be seated at a restaurant table and served a very large bowl of Hot & Sour soup. You will be asked to eat the entire bowl, or as much of it as you can eat if you do not care to eat the whole bowl. After you have stopped eating the Hot & Sour soup, you will remain at your table for fifteen minutes so that the Researcher may observe any effects that it has on you. If the Researcher observes any effect, she might ask you to stay for additional observation, but you are free to leave if you wish. It is estimated that participants will be able eat the soup in under 15 minutes and so, with the normal period of observation, will spend a total of approximately 30 minutes at each of second through fifth visits and will spend less than an hour at the first visit.

After your participation at each visit is completed, you will be offered a complimentary (free) dinner at that restaurant's buffet. You may accept the buffet dinner or may decline it as you choose. If you choose to accept the buffet dinner, it must be eaten at that time and cannot be saved until later.

Risks and Benefits

Potential risks of participating in this research study include a burning sensation in your lips, mouth, and esophagus (the tube connecting the throat to the stomach) or heartburn, due to the spicy nature of the soup. It is believed that this risk is minimal for you as you are a consumer of hot & sour soup anyway, outside of the research. There is also a risk that you might be allergic to one or more of the ingredients in the soup. Again, this is believed to be minimal because you eat the soup anyway. There may be other risks associated with your particular health (i.e. if you are diabetic or have certain other diseases). The Researcher has minimized this risk by excluding potential subjects during the initial interview and by dismissing any subjects who disclose such conditions on the medical history form. If the Researcher believes you experienced a problematic reaction, she will contact you over the next few days to monitor your condition.

There might also be a risk of breach of confidentiality. To minimize this risk, you will be assigned an ID number at the first visit. You will be provided with a card with the ID number on it and asked to bring the card with you to each visit, so that you have the number available to you at each visit. Only your ID number, and not your name, will be placed on the medical history form and on the Researcher's form to record her observations each visit. The Researcher will have a list of participants linking names to ID numbers. This list will be used to match information received from your doctor, if any, as described below, and to contact you if follow-up is necessary, as described above. This list will be stored separately from research data in a locked location and will be destroyed after data collection is completed.

It is not expected that participants will experience any direct benefits from participation in this research. It is hoped that society at large will benefit in the long run from the addition to scientific knowledge contributed by this research.

Involuntary Withdrawal

It is possible that the Researcher will withdraw you from further participation in the study whether or not you wish to withdraw. After you fill out the medical history form at the first visit, you will be withdrawn if you disclose any prior conditions that make your participation risky or might confound the results. If that occurs, you will still be offered the complimentary buffet for that evening. If the Researcher observes adverse physical effect on you during any visit or if you report adverse health effects to the Researcher after a session, you will be removed from the study. If you withdraw your authorization for your doctor to disclose information to Dr. Specialist (as described immediately below), you will be removed from the study.

Authorization to Use or Disclose Protected Health Information for Research

Signing this informed consent to participate in the research study that it describes, also authorizes my primary care doctor (whose name and contact information I will separately provide to Dr. Specialist) to disclose any prior history I may have of the particular problems for which Dr. Specialist is looking to Dr. Specialist in order to enable Dr. Specialist to distinguish between reactions to the soup and prior medical problems. This authorization will expire three days after I complete the last experimental eating session for the research study.

This authorization may be revoked at any time by contacting the Investigator at at 1-800-555-5555, or via email to gispecialist@lecom.edu, but that the revocation will not affect any information that may already have been disclosed before then.

If you do not authorize the use or disclosure of your health information, you will be unable to participate in this research study, but it will have no other effect on you.

The Federal Privacy Rule may no longer protect the health information that is disclosed to the recipient if the recipient is not itself covered by the Rule.

For More Information

If you have questions about this research or if you believe you have experienced a research-related injury, please contact Dr. Specialist at 1-800-555-5555, or via email to gispecialist@lecom.edu.

If you have questions about your rights as a research subject, please contact Irv Freeman, Ph.D., J.D., at 724-552-2870, or via email to ifreeman@lecom.edu.

Consent

I certify that I have read this consent document, that I have discussed the research with Dr. Specialist, and that any questions I had have been answered. I consent to participate in this research study.

_____ _____

Signature of Subject Date

Appendix III – Debriefing

Thank You and Additional Information

Thank you for participating in this research study. I hope you found your participation to be interesting and enjoyable.

The purpose of this memorandum is to provide you with one piece of information that was withheld from you until now.

During the informed consent process, you were advised that the purpose of this research project is to "determine whether eating hot & sour soup has any immediate short-term effects on the human body that may be observed immediately following eating the soup."

That purpose statement is true, but it is incomplete and non-specific. The actual purpose is to determine whether eating hot & sour soup has the effect of inducing hiccoughs while eating or immediately following eating. That is the only effect for which we were looking.

You were not previously told that we were looking for hiccoughs because we were afraid that knowledge could have an impact on whether or not you would develop hiccoughs. Now that the data gathering is complete, the full information is being provided to you.

Our procedure in providing you with less than complete information about the research's purpose during the informed consent process was approved by the LECOM Institutional Review Board (IRB). In approving this waiver from the normal requirements for informed consent, the IRB followed the requirements laid out by the Federal government. Specifically, the IRB determined that (1) the research involved no more than minimal risk to you, (2) the waiver would not adversely affect your rights and welfare, and (3) the research could not practicably be carried out without the waiver. Finally, the IRB made sure that I would be providing you with pertinent information (in the form of this memorandum) after your participation.

If you have any questions or concerns about this, please contact Irv Freeman, Ph.D., J.D., Chair of the LECOM Institutional Review Board, at 724-552-2870, ifreeman@lecom.edu.

Thank you,

Dr. G. I. Specialist

1-800-555-5555