#### IRB SYNOPSIS OF PROPOSAL: Gerald D. Redwine, MEd., MT(ASCP)

**Prediabetes Testing of Traditional College Students**

1. This pilot study will solicit volunteers from Texas state University-San Marcos CLS students to represent the traditional college student. CLS students were selected because they are highly motivated juniors and seniors in a moderate to high stress curriculum. Stress is a known factor adding to diabetes complications. Any psychological trauma from blood collection will be minimized since these students are trained to collect samples from each other during the course of our CLS program. Furthermore, this research will offer opportunities for our CLS students to witness firsthand the research processes of making laboratory tests routine. It will also offer them firsthand opportunities for comparative studies and test verification that are part of their CLS curriculum. For the researcher this two years rigorous program offers opportunity to observe changes over that period of time relating to prediabetes in the students.

The students are diverse in age, gender, and ethnicity. The expected number of students is between 20 and 40, 18 years old or older, both male and female from diverse ethnic backgrounds. Ideally the students will be tested at the end of four semesters when their stress levels are highest. However, the pilot study will begin with the student volunteers currently in our program and continue with those entering September 2011 until their graduation in August 2013.

Initially the CLS faculty will obtain a questionnaire (Appendix B) concerning the students’ diet, exercise, pregnancy status (females), and symptoms of diabetes approximately March 2011 through November 2011. Pregnant students will be discreetly dismissed from the study. Following this initial questionnaire, trained CLS faculty will take BMI measurements utilizing the students’ height and weight from an accurate scale. To minimize discomfort blood samples will be collected by the Texas State University-San Marcos Student Health Center Laboratory but the test will be analyzed by Texas state CLS faculty. A posttest (Appendix C) will be administered by CLS faculty in July of their final semester in the CLS program of individuals determined to the diabetic or prediabetic.

1. Clinical Laboratory Science (CLS) faculty will solicit volunteers during class from Texas state University-San Marcos CLS students. These students will represent the traditional college student in this pilot study. The information will be confidential, numerically coded, and locked in a cabinet of the primary investigator (PI). Only those identified as prediabetics or diabetic will be known by the primary investigator (PI) Gerald D. Redwine and that student. To prevent coercion the consent form (Appendix A) will stress that non-volunteers will not be penalized in any manner.

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1. The students will be pretested(Appendix B) concerning their diet, exercise, and symptoms of diabetes. Next, the students will be tested on overweight tendencies by measuring their body mass index (BMI). The students will then be screened for prediabetes with a fasting plasma glucose (FPG) test; the standard test that indicate diabetes. In addition, a hemoglobin A1c (HbA1c) called glycolated hemoglobin, which evaluates damaged red blood cell (RBC) proteins caused by the elevated glucose levels10 plus a lipid panel will be tested and used in a correlation study as to their relevance to indicate prediabetes. All students with elevated FPG will be informed of their status and advised to seek counsel from their primary care physician and request confirmation of prediabetes in a laboratory certified by the Clinical Laboratory Improvement Amendments (CLIA). Each semester the students will be tested for elevated FPG until their last semester prior to graduating from Texas State University-San Marcos CLS program or in the event they develop prediabetes. Finally, any prediabetic students will be post tested for changes in diet and exercise as a result of this study.

Volunteers will fast overnight (12 hours minimum). One 5 mL EDTA and one 10 mL clot tube will be collected by personnel in the Texas State University-San Marcos Student Health Center Laboratory the next morning. The 10 mL tube will be analyzed for glucose and a lipid panel. The five mL EDTA samples will be analyzed for hemoglobin A1c. The analysis of this study will be divided into two parts; questionnaire and data analysis. The CLS students together as a university sample will be analyzed using SPSS by univariate analysis on each variable listed in the questionnaire with elevated fasting blood glucose being the outcome (dependent) variable.

1. My assessment of the risks and benefits to the students is based upon more than 20 years of experience of performing phlebotomy and American Society of Clinical Pathologist (ASAP) certified Clinical Laboratory Scientists for 15 years plus more than three years training students to do phlebotomy. The risks to the students are minimal, but include possible nerve damage via blood draw and injury from fainting. These problems are offset with the professionals at the Texas State Student Health Center who will collect the samples. In addition, the students have been trained in phlebotomy with practice on one another by me and other faculty and our clinical laboratory science (CLS) program.
2. Because a positive test may cause anxiety, they will be advised to seek confirmation and counsel with their primary care physician. Confidentiality is provided in this study through use of study numbers. Each participant will be given a copy of their signed consent form with their assigned study number. The only person who will have this information is Prof. Gerald D. Redwine who is an instructor in the CLS program. Anonymity is not assured. However, student will not be required to provide their Texas State University ID numbers or any personal data unrelated to the study nor will the information be linked to the student for reasons other than counseling.
3. Any psychological trauma from blood collection will be minimized since these students are trained to collect samples from each other during the course of our CLS program. Furthermore, this research will offer opportunities for our CLS students to witness firsthand the research processes of making laboratory tests routine. It will also offer them firsthand opportunities for comparative studies and test verification that are part of their CLS curriculum.
4. Participants will be given a compensation to include a value of $5 each visit. They will also benefit by knowing they are contributing to science and knowing they can prevent type 2 diabetes mellitus (DM).
5. The risk to the students, while minimal, includes possible nerve damage via blood draw and injury from fainting. These problems are offset with the professionals at the Texas State Student Health Center who will collect the samples. In addition, the students have been trained in phlebotomy with practice on one another by me and other faculty and our clinical laboratory science (CLS) program.

There is also a possibility that the students discover they are prediabetic. This may be disturbing to the student, but it also may benefit the student by knowing this information. If this occurs, they will be given contact information for the Texas State University Counseling and Career Services Center. They will also be advised on getting confirmation and counsel from a primary care physician. Those who participate in this study will also benefit by knowing they are contributing to the knowledge of science in the field of their study.

1. Test for prediabetes in this study will be analyzed on our department Roche Cobas Mira S chemistry analyzer.
2. None applicable.
3. Although this is a pilot study, I Gerald D. Redwine, am also the supervising faculty.
4. This project has not previously been submitted for IRB approval.
5. With the exception of the student's identity all materials for this research will be accessible by the CLS faculty listed below.

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**In addition to this synopsis, you are required to submit all relevant documentation for review. This may include, but is not necessarily limited to: 1) recruiting documents (e.g., flyers, letter, e-mails, brochures, etc.), 2) a consent form, 3) an assent form, 4) letters of approval from relevant organization(s), 5) surveys/instruments/questionnaires, esp. those created by the researcher, 6) a list of questions that the researcher may ask (e.g., focus groups questions, questions for qualitative studies, etc.), and 7) all documents in translated versions.**