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**Protocol Title:** Smoking Cessation Following Text Message Intervention in Pregnant Women  
**Protocol Status:** CLOSED  
**Date Submitted:** 12/05/2016  
**Approval Period:** Draft  
**Important Note:** This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.

**\*\*\* Subject Population \*\*\***

**Subject Population(s) Checklist**

**Select All That Apply :**

- X Adults  
 Cognitively Impaired Subjects  
 Employees (specifically targeted)  
 Fetuses  
 Minors (under 18)
- X Pregnant Women  
 Prisoners  
 Students (specifically targeted)  
 Terminally Ill Subjects  
 Wards of the State  
 Other (e.g., non-English speaking or any population that is not specified above)

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**\*\*\* Expedited Paragraphs \*\*\***

To request an Expedited Review, check the appropriate category(ies) below. Provide justification for your request for Expedited Review.

To qualify for expedited review, research activities must (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories below.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a) Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - b) Research on medical devices for which
    - (i) An investigational device exemption application (21 CFR Part 812) is not required; or
    - (ii) The medical device is cleared/approved for marketing and the medical device is being used in

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accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

3. Prospective collection of biological specimens for research purposes by non-invasive means.

**EXAMPLES:** (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

**EXAMPLES:** (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- X 8. [FOR IRB use only]. Continuing review of research previously approved by a convened IRB only when condition (a), (b), or (c) is met.
- a) Previously approved research where
- (i) The research is permanently closed to the enrollment of new subjects;
- (ii) All subjects have completed all research-related interventions; and
- (iii) The research remains active only for the long term follow-up of subjects.
- b) Previously approved research where no subjects have been enrolled and no additional risks have been identified.
- X c) Previously approved research where the remaining research activities are limited to data analysis.
9. [FOR IRB use only]. Continuing review or research not conducted under an investigational new drug application or investigational drug exemption where expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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**\*\*\* Background, Purpose, Study Procedures \*\*\***

**Title**

Smoking Cessation Following Text Message Intervention in Pregnant Women
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**Complete Sections 1 - 16. In sections that allow reference to sponsor protocol or grant, clearly state section and page numbers. Any information that is different or specific to the local site should be in the SLU application. Specify N/A as appropriate. Do not leave any required sections blank.**

**1. Background**

Page numbers from a sponsor's protocol/grant may be referenced in 1a and 1b.

- a) Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable. Investigator Initiated studies must cite references in the response provided or attach a bibliography. \* <a

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href="javascript:showPopUpdata('HELP','Application Consideration:

In this question the IRB requires a brief introduction with supporting background information to describe your study. Do not include overly lengthy descriptions.

**Investigator Initiated studies (i.e., the Principal Investigator has conceived, designed, and is conducting the research) are required to cite references in the response or should upload a referenced bibliography in the Attachments section.)">?HELP?\***

Smoking during pregnancy has been shown to have detrimental effects on both the mother and the fetus. The perinatal period presents a critical opportunity to educate and support the mother as she attempts quit. Current studies suggest a median quit rate of only 4.9% in women receiving usual care (Cognitive Behavioral Therapy, CBT), but a number of studies have investigated new interventions in addition to usual care to help increase compliance with smoking cessation. Pharmacological aids such as nicotine replacement therapy (NRT) and bupropion are recommended as potential options by the American College of Obstetrics and Gynecology since they are considered safer than continued smoking during pregnancy. Studies thus far on smoking cessation with the help of electronic devices have demonstrated mixed results; however, the impact of texting in the pregnant population in combination with CBT and pharmacological therapy has yet to be assessed.

Smoking during pregnancy has been shown to have detrimental effects on both the mother and the fetus. Cigarettes contain over 3000 compounds many of which can cause risk to pregnancy. However, the nicotine and carbon monoxide components are of primary concern.1-8 Nicotine releases epinephrine, which results in a decrease in uterine blood flow and an increase in uterine resistance. There is also decreased production of fetal nitric oxide resulting in lower blood flow to the fetus and leading to decreased birth weight, length, and head circumference compared to non-smokers.9

Studies have proven that exposure to tobacco can increase the risk for placental abruption, placental previa, preterm birth, antenatal death, sudden infant death syndromes, attention-deficit/hyperactivity disorder and asthma.2-8 Compared to children of non-smoking mothers, children of mothers who smoked during pregnancy had a higher BMI and increased odds for being overweight at 4-years of age; however, in the children whose mother quit smoking during pregnancy there was no increased risk of increased BMI or being overweight compared to the children of non-smoking mothers.10 According to the data from the 2009 Pregnancy Risk Assessment and Monitoring System (PRAMS) approximately 12.4% of pregnant women with live births reported smoking during the last three months of pregnancy (PRAMS).11 Of the 25% of women who smoked in the 3 months prior to pregnancy, 52% quit during pregnancy; of those, 44% relapsed within 6 months after delivery. The perinatal period presents a critical opportunity to educate and support the mother as she attempts quit.

Current studies evaluating rates of smoking cessation in pregnant women show less than ideal results. A primary analysis of 12 pooled trials found a median quit rate of 4.9% in women with usual care. This rate increased to 13.2% in patients that received tailored self-help intervention.12 To help increase compliance with cessation, studies have investigated new interventions as part of the usual care provided to pregnant patients that continue to smoke. One study looked at including a 15-minute video and provider prompting at baseline and one month. Although a higher percentage of patients in the intervention group had a higher 30-day abstinence rate at 2-months post baseline, the finding was not significant (26.1% vs 10.5%, p=0.12) although the study did not discuss if this was an appropriately powered sample size.13 Another study looking at the combination of smoking cessation education, physical activity counseling and supervised exercise found a 25% abstinence rate at 8-months gestation.14 The use of NRT has also been studied. One study found that CBT plus NRT verses CBT alone was effective at 7-weeks (24% vs 8%, p=0.02) and 38-weeks' gestation (18% vs 7%, p=0.04), unfortunately there was no benefit at 3-months post-partum (20% vs. 14%, p=0.55).15

The use of pharmacological aids for smoking cessation is recommended as a potential option

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by the American College of Obstetrics and Gynecology. Currently, NRT products and bupropion are appropriate options during pregnancy and are the most utilized therapy for cessation during pregnancy.<sup>16</sup> Although classified as pregnancy category-D medication, NRT patches are often used to assist the pregnant patient in smoking cessation when CBT is not successful. A review looking at 4-studies that examined pregnancy outcomes after NRT, found a significant decrease in the risk of preterm delivery and low-birth weight compared to active smokers. NRT is considered safer than continued smoking since it only provides nicotine whereas smoking provides nicotine plus over 3000 other chemicals. It has also improved cessation rates near the quit date compared to CBT in obstetric patients.<sup>17</sup> Similarly, bupropion has improved cessation rates in non-obstetric patients and has not been associated with malformations or abnormal pregnancy outcomes.<sup>18-21</sup>

The transtheoretical stages of change assessment is beneficial to help determine a patient's readiness to quit. Data has shown that the stages predict preparation for cessation and successful cessation.<sup>22</sup> In the precontemplative stage, patients are not willing to consider smoking cessation. The contemplative stage is defined as patients considering smoking cessation but not ready to set a quit date. Preparation stage occurs when patient is ready to set a quit date within the next 30 days. In the action stage, patients have been smoke free for less than six months. Maintenance stage is cessation longer than 6 months. Relapse is when patients have starting smoking again after being in the action stage. In other obstetric smoking cessation literature, relapse has been defined as smoking more than 5 cigarettes or smoking more than 5 times since cessation.<sup>17</sup>

Mobile technology is common place in today's society. According to the 2013 Nielsen report, 94% of all Americans 16 years of age or older use a cellular phone with more than half of those being smart phones.<sup>23</sup> A total of 96% of phone owners have a data plan included. In 2012, the average monthly usage included 164.5 calls, 644.1 voice minutes, and 764.2 text messages. Ownership of cell phones and high tech devices extends to all socioeconomic classes, and the ease and affordability has made cell phone use common for all races and income brackets. When looking at text message specifically for race 79% of whites, 85% of Blacks and 87% of Hispanics report text messaging. When looking at household income 78% of those making < 30K, 80% of those making between 30k-50k, and 88% of those making greater than 50k are active texters.<sup>24</sup> African Americans are more likely than the general population to own smart phones (71% vs. 62%) and are 44% more likely than the broader market to create a social media profile. Over a monthly basis, African Americans also spend 24% more time on their phone, 12% more time on email, and 10% more time on the internet.<sup>25</sup> Hispanics text the greatest of all ethnic groups at 943 text messages per month.<sup>26</sup> Based on this data, it is apparent that mobile phone messaging is a potential convenient and cost-effective way to interact with patients of all races and income levels.

Results of current studies looking at smoking cessation with the help of computer or other electronic device are mixed.<sup>27</sup> Several trials have looked at the use of text-messaging based smoking cessation programs. One randomized controlled pilot trial of 151 daily smokers interested in quitting found a non-clinically significant difference in cessation rates at 3 months between the intervention and control groups (11% versus 4%), this study was not powered to detect a statistical difference.<sup>28</sup> A small pilot study evaluating Text2Quit, an automated, personalized, and interactive program that sends texts and emails over the course of 3 months, reported liking the program at 2 and 4 weeks after enrollment (91% and 82%, respectively) and 75% of participants reported reading most or all of the messages sent.<sup>29</sup> Unfortunately, the majority of participants admitted to smoking at the 4-week visit. The txt2stop study was a trial of 5800 smokers that were randomized to receive text messages that were comprised of motivational and behaviour-change support versus the control group who received text messages unrelated to quitting. At 6-months abstinence was significantly increased in the intervention group versus the control group (10.7% vs. 4.9%;  $p < 0.0001$ ).<sup>30</sup>

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- b) Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.

N/A

## 2. Purpose of the study

- a) Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.

We propose an 18-month, randomized, open-label evaluation of the impact of texting to pregnant, underserved, cigarette smokers on smoking cessation rates. Patients will be eligible if they have a confirmed pregnancy, obstetric care provided at the St. Mary's Health Center Maternal Fetal Care Center, are English speaking, at least 18 years of age, are in the preparation stage of change and willing to set a quit date within 30 days and before 35 weeks gestation, and have a cellular phone that is capable of receiving text messages. Patients will be randomized to either the texting group or control group. A baseline carbon monoxide level will be obtained. The patient, regardless of group, will have the standard of care smoking cessation visit. If the pharmacist, physician, and patient deem that pharmacotherapy is appropriate, they will receive nicotine replacement therapy patches or bupropion free of charge in 2-week intervals. Patients in the intervention group will receive text messages focused on smoking cessation and pregnancy. Patients will be seen on a bi-weekly schedule to obtain additional vouchers for patches or for bupropion, meet with the pharmacist, and complete a carbon monoxide exhalation test. These visits will be continued until the pharmacotherapy course is complete. Patient information on additional barriers to stop smoking will also be obtained including the ongoing use of marijuana and alcohol. This information is also collected as standard of care for all pregnant women seen by our group.

Page numbers from a sponsor's protocol/grant may be referenced in 2b and 2c.

- b) List your research objectives (specific aims & hypotheses of the study).

The primary objective of the study is to evaluate the impact of a text-message service on smoking cessation in medically underserved, obstetric patients when added to the usual care of pharmacist-driven CBT smoking cessation program and smoking cessation pharmacotherapy with either the nicotine replacement patch or bupropion. The smoking cessation rate will be verified by exhaled carbon monoxide levels (<8ppm) at 2 weeks of the patients quit date. Secondary objectives of the study include (1) a comparison of self-reported cessation versus verified cessation from the exhaled carbon monoxide level, (2) self-reported cessation rates at 1 month, 3 months, and delivery as verified by exhaled carbon monoxide levels, and (3) change in exhaled carbon monoxide levels from baseline to 2 week follow-up, (4), to better understand which patients may face additional barriers with tobacco cessation during pregnancy and ongoing use of marijuana and alcohol may be predictive.

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- c) Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.). If the study is investigator-initiated, a timeline for individual subject recruitment, follow-up, and analysis for the study is required. Also, indicate if the subjects will be randomized.

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We propose an 18-month prospective, randomized, open-label evaluation of the impact of texting to pregnant, underserved, cigarette smokers on smoking cessation rates.

March 2014: Obtain IRB approval  
 April 1 2014: Begin enrolling patients via randomization  
 April 31st, 2015: Cease enrollment of new patients  
 June 1st 2015: Final collection of all data for all enrolled patients  
 Summer 2015: Data analysis, manuscript preparation

d) **If subjects will be given placebo, please justify placebo use. \*?HELP?\***

N/A

### 3. Study Procedures

- a) **N** Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator) OR does this study involve conduct of research at multiple sites?  
 Is SLU acting as a coordinating center for other sites OR is the SLU PI a direct recipient of a federal grant for this research? If yes, complete and attach the Supplemental Application for Coordinating Center Activities.  
 Will the SLU site be participating in all parts/procedures/arms of the study?

**If No, explain what SLU will NOT participate in:**

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Page numbers from a sponsor's protocol/grant may be referenced in 3b, 3c, and 3d.

- b) **Describe all the procedures, from screening through end-of-study, that the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and which are standard of care. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).**

This is a randomized, open-label, prospective trial that will evaluate the impact of texting to pregnant, underserved, cigarette smokers on smoking cessation rates. It will be conducted over 18-months, with subject recruitment over 12 months, at St. Mary's Health Center Maternal Fetal Care Center. Potential patients will be identified through EPIC chart review as well as from referrals from providers. These patients will be screened for inclusion and exclusion criteria through a chart review as well as meeting with pharmacy to determine the patient's stage of change and willingness to set a quit date within the next 30 days. Informed consent will be obtained if the patient is eligible and willing to participate.

As part of routine care at the Maternal Fetal Care Center, pregnant women that are active smokers are encouraged to quit. If the patient is interested in quitting smoking, the physician or pharmacist will schedule a smoking-cessation consultation visit with maternal-fetal clinical pharmacist. During this pilot study, women who have expressed interest in quitting and meet the inclusion and exclusion criteria will be approached and offered enrollment in the smoking cessation study. Patients who consent will be randomized to either the texting group or control group. For randomization purposes, an equal number of notecards will be made for the two groups. We will use a random number generator to help with patient randomization. These



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groups. We will use a random number generator to help with patient randomization. These numbers will be placed in a sealed envelope and shuffled. At the time of patient inclusion, an envelope will be selected by the pharmacist. However, if a patient declines receiving text messages but consents to participate in the pharmacist driven CBT and NRT, she will be enrolled in the standard of care group. A baseline carbon monoxide level will be obtained.

#### Description of Usual Care

The patient, regardless of group, will have the standard of care smoking cessation visit with the clinical pharmacy specialist or PGY2 ambulatory care resident. The visit will include

- Medication reconciliation
- Review social history which includes use of street drugs and alcohol, allergies, and vaccine history
- Obtain smoking history that included current amount smoking, changes in smoking habits during this pregnancy, number of years smoked, quit attempt history, and use of previous smoking cessation aids
- Design a quit plan that includes setting a quit date within the next 30 days, obtain follow-up contact information, identify motivators/triggers/barriers, discuss withdrawal symptoms, develop plan for management of withdrawal symptoms, develop a plan for behavior modifications, discuss rewards, handling of relapse, medication options for cessation during pregnancy, and education on purpose, proper use, potential maternal and neonatal adverse events

If the pharmacist, physician, and patient deem that pharmacotherapy is appropriate, the patient will receive a 2 week supply if using NRT or 3 week supply if using bupropion. The smoking cessation pharmacotherapy will be supplied free of charge to the consenting participants. If the patient is prescribed NRT patches, the medication will be provided in two week intervals. If the patient is prescribed bupropion, the medication will be provided for a 3 week supply with the initial dispensing and 2 week supply thereafter. Dosing and length of treatment will follow package insert approved dosing. Patients will receive a voucher to take to the Clayton Health Services Pharmacy located across the street from the Maternal Fetal Care Clinic to receive either medication at no cost.

Demographics, social history, gestation age at enrollment, estimated due date, medications at enrollment, past medical history, and obstetric history include gravity and parity will be obtained from the EPIC medical record. Patients will be asked about smoking history, time to first morning cigarette, previous quit attempts, previous experience with cessation pharmacotherapy, motivators, triggers, and barriers during initial visit.

#### Intervention Group

Patients in the intervention group will receive text messages focused on smoking cessation and pregnancy. An initial text message will be sent 2-3 days prior to their quit date, with subsequent message being sent, 1 day prior to the quit date, on their quit and continued in a de-escalating fashion until they deliver. Patients will also receive text messages when they need to replenish their smoking cessation patches. Patients will be contacted through Google Voice which is a Google system requiring a secure login and password. The user name for this account is ssmhcrx@gmail.com and the phone number which will be contacting the patient is 636-486-6774.

#### Follow-up phone calls and visits for Intervention and Control Groups

Usual follow-up includes a telephone call to the patient within 3 days of the quit date then weekly for 2 weeks afterwards. Each phone call includes assessing current smoking status, identifying withdrawal symptoms and how the patient handles them, review of behavior modifications, assessment of reward planning, medication reconciliation, assessment for adherence, concerns, and adverse events with therapy, and education as needed on the above areas.

Patients will be scheduled to return to the Maternal Fetal Care Clinic 2-weeks after their quit date to obtain additional voucher to refill patches or bupropion. At each voucher pick-up, the patient will need to report her smoking status then perform an exhaled carbon monoxide level.

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Patients will be continued to be seen on a bi-weekly schedule to obtain additional vouchers for patches or for bupropion, meet with the pharmacist, and complete a carbon monoxide exhalation test. These visits will be continued until the pharmacotherapy course is complete.

As the only intervention in this study is text messaging and the primary outcome measure is smoking cessation, we plan to continue the study through the patient's delivery. The patient may discontinue enrollment at any time.

Text Message Intervention  
Smoking Cessation Text Messages

\*Prior to quit date

\*Inform others:

Congratulations, your quit date is in 3 days! Let friends and family know you are planning to quit and how they can help support you. Support is one of the key pieces to quitting smoking!

\* Remove reminders:

Congratulations, your quit date is in 2 days! Get rid of things such as lighters, ashtrays, and cigarettes. Clean your car, house, and clothes so they don't smell like cigarette smoke when you quit.

\*Prepare for cravings:

Congratulations, your quit date is tomorrow! Remember that cravings will only last about 20 minutes, so have activities planned to distract yourself! Do a crossword puzzle, take a walk, clean the house, eat a healthy snack if you're hungry, etc.

\* Reasons why you're quitting

Congratulations, TODAY is your quit date! Look at the list of reasons you made for quitting and remind yourself of what a great thing you are doing for yourself and for baby! Start using your (patch) today now that you are ready to be smoke free. We are here to answer any questions (phone #)

\* During quit attempt

\*Mid-afternoon of quit date

Starting to have a craving? Go for a brief walk outside and breathe in some nice fresh air! You can do this!!

\* Day 2

Wow! You made it through day 1! Keep up the great work. Remember that cravings don't last more than 20 minutes, so do something fun or work on a project to distract yourself!

\* Day 3

Yeah! 3 smoke free days! Your carbon monoxide level in your blood has decreased to normal, which means your blood oxygen level has increased to normal. More oxygen for you and for baby!

\* Day 5

Have you noticed that your sense of taste and smell has improved? Keep up the great work! Remember that mixing up your routine during the times you used to smoke can help make it easier to stay smoke free!

\* Day 7

Congratulations! You have gone 1 week without smoking! Your body is already benefitting from quitting smoking, such as lower heart rate and blood pressure! Keep up the great work and contact your clinical pharmacists with any questions!

\* Day 10

You are doing great! Remember, if you have a slip up and smoke a few cigarettes, don't be discouraged! This doesn't mean you have failed and should keep smoking—just get back on

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track right away! Think about what triggered it and how you will deal with it next time. We can help!

\* Day 14

Congratulations! You have gone almost 2 weeks without smoking! Don't forget to pick up your (patches, gum) from the office. You may notice that your lung function and circulation is starting to improve. If you are breathing easier, baby is getting more oxygen too!

\* Day 21

Congratulations! It has been 3 weeks since your quit date! Think about how much money you have saved on cigarettes so far and treat yourself to something special! You may notice less withdrawal symptoms and cravings as well. Keep up the good work!

\* Day 28

Congratulations! You have been smoke-free for almost 1 month! Don't forget to pick up your (patches) from the office.

Check-ins every 2 weeks thereafter

oSimilar reminders every 2 weeks until therapy is complete

Delivery

If available, delivery details will be abstracted from the patient charts and shall include gestational age at delivery, fetal weight, APGAR scores, and umbilical cord gases.

- c) **If the proposed study is a clinical trial where a drug, vaccine, device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional subjects. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.**

N/A

- d) **Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. For full board, unfunded studies describe sample size determination and power analysis. If none, please justify.**

Power Calculation

Based on previous experience, we anticipate 30% of patients will stop smoking at 2 weeks and anticipate texting will increase cessation rates by an additional 5%. Using G\*Power, based on a Chi square test, alpha of 0.05, power of 0.8, and medium effect size of 0.5, we estimate needing 52 patients. We anticipate 15% lost to follow-up or drop outs, so we anticipate needing 60 patients for this pilot project.

G\*Power is a free online statistical tool for calculating power in social, behavioral, and biomedical sciences.<sup>32</sup>

Outcomes and Statistical Analysis

Primary Outcome- Smoking cessation rate verified by exhaled carbon monoxide levels (<8ppm) at 2weeks of quit date between texting and control group

Statistical Analysis- Chi-squared or Fischer's Exact Adjusted for confounders: multiregression

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Statistical Analysis- Chi-squared or Fischer’s Exact Adjusted for confounders: multiregression analysis

Secondary Outcomes-Comparison between self-reported quit rates and verification through exhaled carbon monoxide levels  
Statistical Analysis- McNemar’s

Secondary Outcome-Change in exhaled carbon monoxide levels between baseline and 2 weeks  
Statistical Analysis-Paired t-test

Secondary Outcome-Comparison for demographics and verified cessation rates at 2 weeks  
Statistical Analysis-Parametric: t-tests, Nonparametric: Chi-squared or Fisher’s exact

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e) State if deception (including incomplete disclosure of study purpose/procedures) will be used. If so, describe the nature of the deception and provide a rationale for its use. Also, describe debriefing procedures or justify a waiver of the requirement to debrief. NOTE: for studies using deception, an alteration of consent must be justified in the Informed Consent section of the protocol (#13) and the debriefing script/statement must be uploaded in the Attachments section (#16). <a href=http://www.slu.edu/Documents/research/irb/Deception\_Incomplete.doc target=\_blank > See IRB Deception Guidelines.

f) Is there an accepted standard of care and/or standard practice at SLU for the condition/disease/situation being studied? This information will assist in comparing the risk/benefit ratio of study procedures relevant to usual care that would be received outside of the research context. **\*?HELP?\*** Y

If yes, please describe the standard of care and standard practice at SLU for the condition/disease/situation being studied.

The smoking cessation program is the standard of care.

g) Does this study involve any diagnostic imaging, labwork or genetic testing that could result in clinical discovery (diagnoses, genetic mutations, etc.)? Note that this could include discovery that is expected (related to the research) or incidental (not related to research aims, but possible, like a mass/shadow found in imaging despite not looking for it). N

If yes, please describe and include whether there are plans to share findings with study participants.

h) Is this study subject to the NIH Genomic Data Sharing Policy? N

The NIH GDS policy applies to all NIH-funded research that generates large-scale human genomic data as well as the use of these data for subsequent research and includes: genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic and gene expression data, irrespective of NIH funding

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mechanism. [Click here for more specific examples.](#)

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**\*\*\* Radioisotopes or Radiation Machines \*\*\***

You have not selected the Radioisotopes option in the General Checklist. If you would like to add Radioisotopes information, please select the option to enable this section.

**4. Radioisotopes or Radiation Machines**

In this section, investigators must enter all radiation usage associated with the protocol.

Important: Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-223", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). In these cases, submission to the RSO/RSC should occur first, even before submission to IRB. For more information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

(1) It is the responsibility of the PI to assure the accuracy and completeness of the data submitted in this section, consistent with guidelines provided below. (2) For projects requiring radiation procedures, please refer to this guidance.

- a) **If applicable, list and quantify the radiographic diagnostic and therapeutic procedures associated with this protocol by clicking "Add" and adding to Table 1 below. (Includes X-ray, fluoroscopy, CT, radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.)**

- b) **Total estimated research radiation dose \* :**

\* Calculate from the table above by adding the Effective Dose Subtotals for all procedures.

NOTE: Informed Consent Radiation Exposure Risk Statement- The applicant must insert the appropriate Informed Consent Radiation Exposure Risk Statement template language into the SLU IRB Informed Consent, inclusive of applying the total estimated research radiation dose specified in item b) from the table above, as instructed in the SLU IRB Informed Consent Template. Contact the IRB Office at 977-7744 or irb@slu.edu with any questions.

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**\*\*\* Devices \*\*\***

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**5. Devices**

- a) Please list in the space below all investigational devices to be used on subjects during this study.
  
  - b) Please list in the space below all FDA approved devices to be used on subjects during this study.
- 

**\*\*\* Drugs, Reagents, Chemicals, or Biologic Products \*\*\***

**6. Drugs, Reagents, Chemicals, Biologic Products, or Dietary Supplements, Vitamins, and Other Food Agents**

Pilot	Phase I	Phase II
Phase III	Phase IV	X Not Phased

List placebo if it is considered a drug (contains more than inactive ingredients). For example, normal saline is considered a drug that should be listed, whereas placebo tablets are usually inert ingredients that do not need to be listed.

- &nb Please list in the space below all investigational drugs, reagents or chemicals to be administered to subjects during this study. Attach all applicable Investigator Brochures in section #16 (Attachments).
  
- &nb Please list in the space below all FDA approved drugs, reagents, chemicals to be administered to subjects during this study. Attach all applicable package inserts in section #16 (Attachments).
  
- &nb Please list in the space below all dietary supplements, vitamins, minerals, or foods to be administered to subjects during this study.

Please read the IND Statements.

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**\*\*\* Other Levels Of Review \*\*\***

**7. Other Levels Of Review**

**1. University Radiation Safety**

Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-223", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). For information on how to submit for radiation safety review, see RSC instructions or

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contact the Radiation Safety Officer at 977-6895.

**Not Applicable**

**Yes, study involves radioactive materials (per instructions, submit to RSC before IRB)**

## 2. Institutional Biosafety

Experiments involving the deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules (e.g., Gene Transfer), or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules, or Microorganisms containing Recombinant or Synthetic Nucleic Acid Molecules and/or infectious agents (including select agents and toxins as defined by CDC and/or Animal and Plant Health Inspection Service (APHIS)) into one or more human research participants must be reviewed by the SLU Biological Safety Officer. Most of these protocols also require review and approval by the SLU Institutional Biosafety Committee (IBC). Please contact the SLU Biological Safety Officer at 977-6888 for more information.

**Not Applicable**

**Yes, study requires Institutional Biosafety review**

## 3. Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee

Saint Louis University Hospital requires that all research involving the administration of medications within the hospital (including outpatient areas such as the Emergency Department, Outpatient Center, Saint Louis University Hospital-South Campus, etc.) be reviewed and approved by the Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee and that study drugs are received, stored, prepared, and dispensed by the Hospital's Department of Pharmacy Services. Please contact the Investigational Drug Services Clinical Pharmacist at 268-7156 or SLUH-IDS@ssmsluh.com for more information.

**Not Applicable**

**Yes, study requires PTNT review**

## 4. Saint Louis University Hospital

All research involving Saint Louis University Hospital, including inpatient or outpatient services and medical record access, requires approval from the Saint Louis University Hospital Research Review Committee prior to study initiation. This effort is coordinated through the Clinical Trials Office via eRS. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. Documents should be submitted as soon as possible, or at the latest, concurrently with IRB submission. Please contact the Research Compliance Office at 577-8113 or sluh.research@ssmsluh.com or the SLU Clinical Trials Office at 977-6335 or clinical-trials-office@slu.edu for more information.

**Not Applicable**

**Yes, study requires Saint Louis University Hospital review**

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**5. SSMSL**

All research involving SSMSL locations (including Cardinal Glennon), including inpatient or outpatient services and medical record access, requires approval from the SSM STL or SSM Cardinal Glennon Research Business Review (RBR) prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study. Please contact the SSMSL Office at 989-2058 or Marcy\_Young@ssmhc.com for more information.

**Not Applicable**

- X **Yes, study requires RBR review**

**6. Saint Louis University Department of Marketing**

To list your clinical trial on the SLUCare Marketing website, complete the Clinical Trials Information Form on PDF or online.

- X **I am not interested in SLUCare Marketing services for my study.**

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**\*\*\* Subject Population \*\*\***

**8. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)**

- a) **Expected age range of subjects. (For example ≥ 18 yrs to 90 yrs).**

18-55yrs of age

- b) **Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI).**

100

Exceeding the number listed here is a protocol violation. Prior IRB approval is required if additional participants are to be accrued. If applicable, this number should be consistent with your power analysis described in 3d.

- c) **Number of evaluable subjects to be accrued study wide. \*?HELP?\***

100

- d) **If applicable, state the rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, economically and educationally disadvantaged, or decisionally impaired individuals. Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects.**

The use of pharmacological aids for smoking cessation is recommended as a potential option by the American College of Obstetrics and Gynecology for pregnant women since they are considered safer than continued smoking during pregnancy. . This study will look at adding text messages to see if cessation rates improve.



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Since this study is looking at pregnant women who smoke we would be unable to perform this study without the inclusion of pregnant women.

- e) **If women, minorities, or minors are not included, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc. If federally funded reference appropriate section of the sponsors protocol/grant. \*?HELP?\***

Minors are excluded from participation because the standard of care medications are not FDA approved for minors.

- f) **If any specifically targeted subjects are students, employees, or laboratory personnel, specify the measures being taken to minimize the risks and the chance of harm to these potentially vulnerable subjects.**

- g) **Describe how potential subjects will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). How will potential participants learn about the research, and how will they be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? Upload recruitment materials in the Attachment Section (#16). Important to remember: potential subjects cannot be contacted before IRB approval. NOTE: The use of SLU owned websites in an approved SLU format (e.g., Cancer Center website, etc.) are always approved methods of recruitment.**

Potential patients from the MFM practice will be identified through EPIC chart review as well as from referrals from providers. Recruitment flyers will be posted in the MFM clinic area. These patients will be screened for inclusion and exclusion criteria through a chart review as well as meeting with pharmacy to determine the patient's stage of change and willingness to set a quit date within the next 30 days. Informed consent will be obtained if the patient is eligible and willing to participate.

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**\*\*\* Subject Population \*\*\***

**8. Subject Population (continued)**

**Page numbers from a sponsor's protocol/grant may be referenced in 8h.**

- h) **Inclusion and Exclusion Criteria.**

**Identify inclusion criteria.**

Have a confirmed pregnancy,  
Obstetric care provided at the St. Mary's Health Center Maternal Fetal Care Center,  
English speaking,  
18-55 years of age,  
Are in the preparation stage of change and willing to set a quit date within 30 days and before 35 weeks gestation,  
Have a cellular phone that is capable of receiving text messages, and be willing to pay for any related fees for testing.  
Willing and able to commit to the visit schedule

**Identify exclusion criteria.**

Gestational age > 35 weeks at quit date  
If subjects are in the pre-contemplative or contemplative stages of change or have already received 30

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minute pharmacy education targeted for the quit date in this pregnancy.

- i) **Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.**

No compensation will be paid to the subject

- j) **Describe who will cover study related costs. Explain any costs that will be charged to the subject.**

The carbon monoxide testing will be paid for by St. Louis College of Pharmacy.

All pharmacotherapy, although standard of care will be provided by the College of Pharmacy.  
All visits are standard of care and will not be paid for by the study.  
Subjects will be advised prior to consenting that if their phone plan charges for receiving text messages, the study will not pay for those charges.  
No study related costs will be billed to the subject or their insurance.

- k) **Estimate the probable duration of the entire study including data analysis and publication. This estimate should include the total time each subject is to be involved and the duration the data about the subject is to be collected. If the study is Investigator-initiated, a timeline for individual subject recruitment, follow-up, total time for subject accrual, and data analysis for the study is required.**

Subject participation will vary depending on when in her pregnancy a subject enrolls.  
March 2014: Obtain IRB approval  
April 1 2014: Begin enrolling patients via randomization  
April 31st, 2015: Cease enrollment of new patients  
June 1st 2015: Final collection of all data for all enrolled patients  
Summer 2015: Data analysis, manuscript preparation

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\* \* \* Risks \* \* \*

## 9. Risks

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk".

**Page numbers from a sponsor's protocol/grant may be referenced in 9.1, 9.2, 9.3, and 9.4.**

1.&n Use of investigational devices. Please include the clinical adverse events (AEs) associated with each  
bsp of the devices with an indication of frequency, severity and reversibility. This information can often be  
&nb found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with  
sp& procedures that subjects may experience while in the study.  
nbs  
p

2.&n Use of investigational drugs. Please include the clinical AEs associated with each of the drugs with an

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bsp indication of frequency, severity and reversibility. This information can often be found in the  
&nb Investigator(s) brochure. NOTE: Include any likely adverse effects associated with placebos or  
sp& washout periods that subjects may experience while in the study.  
nbs  
p

3.&n Use of FDA approved drugs, reagents, chemicals, or biologic products. Please include the clinical AEs  
bsp associated with each of the drugs with an indication of frequency, severity and reversibility. This  
&nb information can often be found in the package insert provided by the manufacturer. NOTE: Include any  
sp& likely adverse effects associated with placebos or washout periods that subjects may experience while  
nbs in the study.  
p

4.&n Use of FDA approved devices. Please include the clinical adverse events (AEs) associated with each  
bsp of the devices with an indication of frequency, severity and reversibility. This information can often be  
&nb found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with  
sp& procedures that subjects may experience while in the study.  
nbs  
p

5.&n Describe any risks related to performing study procedures. Please include all investigational, non-  
bsp investigational, and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).  
&nb  
sp&  
nbs  
p

N/A

6.&n Describe any risks related to the use of radioisotopes/radiation-producing machines (e.g., X-rays, CT  
bsp scans, fluoroscopy).  
&nb  
sp&  
nbs  
p

7.&n Describe why this investigational compound/drug/device/procedure's risks/benefits are potentially  
bsp better than standard of care or other common alternatives. Any standard treatment that is being  
&nb withheld must be disclosed and the information must be included in the consent form. \*?HELP?\*  
sp&  
nbs  
p

No treatment is being withheld for those participating in this study. This is a randomized, open label,

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prospective trial. The control group will receive standard of care, consisting of pharmacist driven CBT and provision of NRT patches or bupropion. The experimental group will receive the same with the addition of text messages about smoking cessation.

Smoking during pregnancy has been shown to have detrimental effects on both the mother and the fetus. Cigarettes contain over 3000 compounds many of which can cause risk to pregnancy. However, the nicotine and carbon monoxide components are of primary concern.1-8 Nicotine releases epinephrine, which results in a decrease in uterine blood flow and an increase in uterine resistance. There is also decreased production of fetal nitric oxide resulting in lower blood flow to the fetus and leading to decreased birth weight, length, and head circumference compared to non-smokers.9

Studies have proven that exposure to tobacco can increase the risk for placental abruption, placental previa, preterm birth, antenatal death, sudden infant death syndromes, attention-deficit/hyperactivity disorder and asthma.2-8 Compared to children of non-smoking mothers, children of mothers who smoked during pregnancy had a higher BMI and increased odds for being overweight at 4-years of age; however, in the children whose mother quit smoking during pregnancy there was no increased risk of increased BMI or being overweight compared to the children of non-smoking mothers.10 According to the data from the 2009 Pregnancy Risk Assessment and Monitoring System (PRAMS) approximately 12.4% of pregnant women with live births reported smoking during the last three months of pregnancy (PRAMS).11 Of the 25% of women who smoked in the 3 months prior to pregnancy, 52% quit during pregnancy; of those, 44% relapsed within 6 months after delivery. The perinatal period presents a critical opportunity to educate and support the mother as she attempts quit.

The use of pharmacological aids for smoking cessation is recommended as a potential option by the American College of Obstetrics and Gynecology. Currently, NRT products and bupropion are appropriate options during pregnancy and are the most utilized therapy for cessation during pregnancy.16 Although classified as pregnancy category-D medication, NRT patches are often used to assist the pregnant patient in smoking cessation when CBT is not successful. A review looking at 4-studies that examined pregnancy outcomes after NRT, found a significant decrease in the risk of preterm delivery and low-birth weight compared to active smokers. NRT is considered safer than continued smoking since it only provides nicotine whereas smoking provides nicotine plus over 3000 other chemicals. It has also improved cessation rates near the quit date compared to CBT in obstetric patients.17 Similarly, bupropion has improved cessation rates in non-obstetric patients and has not been associated with malformations or abnormal pregnancy outcomes.18-21

**8.&nbsp; Describe any psychological, social, or legal risks the subject may experience. \*?HELP?\***  
bsp  
&nb  
sp

There is a small risk of loss of confidentiality, but there will be multiple data safeguards to minimize this risk. Any identifiers collected for the study will be destroyed at the completion of the study. Paper records will be protected in a locked cabinet in a locked office and destroyed after the data is entered into the database. A master list will be kept separate.

Page numbers from a sponsor's protocol/grant may be referenced in 9.9 and 9.10.

**9.&nbsp; Special Precautions. Describe the planned procedures for protecting against or minimizing potential risks. If appropriate, include the standards for termination of the participation of the individual subject. Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.**  
bsp  
&nb  
sp

The only patient information stored in the Google Voice system will be a phone number which will be





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b. Will there be language barriers and if so, how will they be addressed?

bsp

Note: If materials are to be distributed to subjects in their native language, please follow SLU's Guidance For Studies Involving Non-English Speaking Subjects.

NOTE: Export control laws include the transfer of technical information and data, as well as information and technology to foreign nationals. If this study has international components, contact the [SLU Export Control Officer](http://www.slu.edu/general-counsel-home/compliance/export-controls) for direction on whether export control policies apply.

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**\*\*\* Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy \*\*\***

**10. Benefits/Alternatives**

a) **Benefits.** Describe the potential benefit(s) to be gained by the subjects and how the results of the study may benefit future subjects and/or society in general. Indicate if there is no direct benefit to the participants.

Subjects may or may not benefit from this research study. Their condition may get better, stay the same, or worsen.

Even though subjects may not receive any benefit, society may benefit in the future because of what the researchers learn from this research study.

b) **Alternatives.** Describe any alternative treatments and procedures available to the subjects should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.

The patient may choose to not participate in the study and would still receive standard office-based management for her pregnancy, including the smoking cessation program.

**11. Procedures to Maintain Confidentiality and Privacy**

Federal regulations require that research materials be kept for a minimum of three (3) years and HIPAA documents be kept for a minimum of six (6) years after the closure of the study. For FDA-regulated or sponsored projects, the PI may be required to keep the data and documents for a longer time period.

**Confidentiality**

To determine whether adequate provisions for confidentiality of data are in place, the IRB must ensure that research materials are stored in appropriate locations throughout the study (during collection, transport/transmission, analysis and long term storage). Research information must be protected using appropriate safeguards based on identifiability of the data and risk associated with the study (See SLU IRB Confidentiality Guidelines).

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For the questions below, please use the following definitions:

**Anonymous/De-identified:** data contain no identifiers, including code numbers that investigators can link to individual identities;

**Coded:** data in which (1) identifying information, such as name or social security number, has been replaced with a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists enabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept separately from coded data; AND/OR

**Identifiable:** data that includes personal identifiers (e.g., name, social security number), such that information could be readily connected to respective individuals.

**a) Electronic (Computer) Data**

Click "Add" to enter data security information for each type of electronic data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data. See the SLU ITS Sensitive Data Guide for acceptable data security methods.

Not Applicable, No Electronic (Computer) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

**b) Hardcopy (Paper) Data**

Click "Add" to enter information for each type of hardcopy (paper) data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data.

Not Applicable, No Hardcopy (Paper) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

**c) If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.**

Code numbers will be used to link the subject to their data. Code and identifiers will be kept separate. PHI will be password protected behind a firewall. Paper copies will be kept in a locked cabinet, in a locked



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office, in a locked suite.

After data is entered into the database, the paper copy of the data will be destroyed.

A master list is kept to link the medical record information to the subject and to obtain follow up information (delivery). The master list is kept separate from the data and will be destroyed when the study is complete.

**d)&n bsp If data or specimens are being shared outside of the research team, indicate who will receive the material and specifically what they will receive (data or specimens).**

The only patient information stored in the Google Voice system will be a phone number which will be identified by a unique participation number for each patient upon her inclusion in the study. The Google Voice system is password protected and only one person will have the password.

The St. Louis College of Pharmacy's IRB provides oversight and may require review of the research records, including patient information.

**e) If samples or data will be provided from an outside source, indicate whether you will have access to identifiers, and if so, how identifiable information is protected.**

N/A

**f) If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).**

**g) If you will be audio/video recording or photographing subjects, provide a rationale as voiceprints and images of faces/unique body markings are considered identifiers. Describe confidentiality procedures, including any restricted access to images and/or the final disposition of the recordings/photos (destruction, archiving, etc.).**

**h) Describe any study-specific (non standard of care) information or documentation that will be put in the participants' medical records for this research (e.g., study visit notes, lab results, etc.). If none, state "not applicable".**

N/A

**i) Are there any information security requirements identified in the project's RFP/Award Notice/Contract? This could include data security, technical safeguards, security controls, NIST, FISMA, CFR, etc.**

If yes, SLU ITS approval is required. Contact [InfoSecurityTeam@slu.edu](mailto:InfoSecurityTeam@slu.edu) to start the approval process.

**Privacy**

Privacy refers to persons having control over the sharing of oneself with others.

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Please indicate how participant privacy will be protected in this study (select all that apply):

Discussion of health related and/or personal information in a private room/area

Research interactions/interventions are conducted in a private room/area

Use of drapes or other privacy measures

Collection of sensitive/identifiable information is limited to the minimum necessary to achieve the aims of the research

Access to study information is limited to the minimum amount of persons necessary to achieve the aims of the research (e.g., access restricted to research team members only)

Consideration of parental inclusion/absence for studies involving minors

Other (please explain):

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**\*\*\* Potential Conflict of Interest \*\*\***

**12. Potential Conflict of Interest**

Indicate whether you, your spouse or dependent children, have, or anticipate having, any income from or financial interest in a sponsor, device or drug manufacturer of this protocol, or a company that owns/licenses the technology being studied. Please remember that you are responding for you and any other investigator participating in the study. Financial Interest includes but is not limited to: consulting; speaking or other fees; honoraria; gifts; licensing revenues; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

Check one of the following (please remember that you are responding for yourself, your spouse, dependent children and any investigator, investigator's spouse and dependent children participating in the study):

- 1)  No equity interest and/or Financial Interest less than or equal to \$5K
- 2)  Any equity interest and/or Financial Interest exceeding \$5K but not exceeding \$25K in the past year or expected in the current year
- 3)  Financial Interest exceeding \$25K in the past year or expected in the current year

Check all those that apply:

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Consulting  
Speaking Fees or Honoraria  
Gifts  
Licensing agreement or royalty income  
Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors  
Other fees/compensation

If you have marked #2 or #3, please contact [coi@slu.edu](mailto:coi@slu.edu) to initiate review of this study and provide the following information:

1. A Conflict of Interest Management Plan.
  - has been approved for all investigators for this study
  - is pending
  - has not been initiated
2. Describe who has, and briefly explain, the conflict of interest and indicate specific amounts for each subcategory checked:

#### Note to Investigator(s) Reporting a Potential Conflict of Interest

#### Investigator(s) must have:

1. Current, up-to-date Conflict of Interest Disclosure Form on file with the SLU Conflict of Interest in Research Committee (COIRC) that describes any financial relationship indicated above.
  - This information must be disclosed on the SLU confidential Conflict of Interest Disclosure Form and reviewed by the COIRC before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIRC.
2. You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIRC for this study. To initiate COIRC review of your study, please contact [coi@slu.edu](mailto:coi@slu.edu).

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#### \*\*\* Informed Consent \*\*\*

#### 13. Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding subject consent. Multiple consents/waivers

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the necessary consent documents and information regarding subject consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

**NOTE:** You may refer to the SLU IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

1) **How is consent being obtained? When and where will the discussion take place?**

The research staff will obtain consent in person. Subjects will be consented at a standard of care visit in St. Mary's Health Center in the MFM offices. The subject will have time to read the consent document. Potential patients from the MFM practice will be identified through EPIC chart review as well as from referrals from providers. These patients will be screened for inclusion and exclusion criteria through a chart review as well as meeting with pharmacy to determine the patient's stage of change and willingness to set a quit date within the next 30 days. Informed consent will be obtained if the patient is eligible and willing to participate.

2) **If the study involves a cognitively impaired population, what steps are you taking to determine that potential subjects are competent to participate in the decision-making process?**

N/A

**Informed Consent**

Title	Consent Type	Attached Date
Approved_Main consent Ver 4	Consent	05/08/2014
Approved_CR2014_Main consent Ver 4	Consent	12/19/2014

Title Approved\_Main consent Ver 4  
 Consent Type Consent  
 Upload Consent Form/Document X Attachment Approved\_main\_ICF\_Ver\_4

Upload your informed consent document. Use the SLU Informed Consent Template to create your consent document. If more than one consent will be used (e.g., adult consent, parental consent, etc.), label the consent documents with these headings to help distinguish them from one another.

**Address the following question. A Yes/No response is not adequate.**

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Title	Approved_CR2014_Main consent Ver 4	
Consent Type	Consent	
Upload Consent Form/Document	X Attachment	Approved_CR2014_main_ICF_Ver_4

Upload your informed consent document. Use the SLU Informed Consent Template to create your consent document. If more than one consent will be used (e.g., adult consent, parental consent, etc.), label the consent documents with these headings to help distinguish them from one another.

**Address the following question. A Yes/No response is not adequate.**

---

**\*\*\* Assent \*\*\***

**14. Assent**

Complete this section if your study includes minors. The Assent Form Template provides guidelines for writing assent documents.

1. Will minors be asked to give assent? If not, please justify.
2. If minors are asked to assent and do not wish to participate, will they still be accrued in the study? If yes, justify.
3. How will the minor's ability to give assent be assessed? (Consider the age and maturity of the minors as well as their physical or mental condition).

**Note:** For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.

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**\*\*\* HIPAA \*\*\***

**15. HIPAA**

Studies that access, receive or collect protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information visit the IRB HIPAA page or refer to the SLU IRB HIPAA Guidance.

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**1. Will health information be accessed, received or collected?**

No health information. HIPAA does not apply.

Yes (continue to question 2).

**2. Which personal identifiers will be received or collected/recorded?**

No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. (Skip remainder of page).

Limited identifiers will be received or collected/recorded (study will likely require a data use agreement). Select Data Use Agreement- INTERNAL or Data Use Agreement- EXTERNAL as appropriate, below.

City/State/Zip codes

Person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)

Age (if subjects are 90+ years)

At least one direct identifier will be received or collected/recorded.

Names

Social Security numbers

Telephone numbers

Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Fax numbers

Electronic mail addresses

Medical record numbers

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers and serial numbers

Web Universal Resource Locations (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable images

**If you are receiving or collecting/recording health information and at least one personal identifier, please**

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continue to complete the sections, below.

**3. Sources of Protected Health Information:**

- X Hospital/medical records for in or out patients
- X Physician/clinic records
- X Laboratory, pathology and/or radiology results  
Biological samples
- X Interviews or questionnaires/health histories  
Mental health records  
Data previously collected for research purposes  
Billing records  
Other

**Please describe:**

**4. If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information.**

- X Not applicable (continue to question 5).  
Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below.  
Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.  
With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

**5. HIPAA Documentation is required for this study. Use the table below to add HIPAA Documents for your study.**

**HIPAA Documents**

HIPAA Documents	Title	Attached Date
HIPAA Authorization	Approved_HIPAA Ver 2	03/12/2014
HIPAA Authorization	Approved_HIPAA Ver 3 3-24-2014	04/07/2014

Title Approved\_HIPAA Ver 2  
 HIPAA Documents HIPAA Authorization  
 HIPAA Form Approved\_HIPAA\_Ver\_2  
 HIPAA Authorization Template

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Title	Approved_HIPAA Ver 3 3-24-2014
HIPAA Documents	HIPAA Authorization
HIPAA Form	Approved_HIPAA Ver 3 3-24-2014
HIPAA Authorization Template	

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**\*\*\* Attachments \*\*\***

**16. Attachments**

In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you.

Possible documents for this protocol could include:

- Bibliography
- Cooperating Institution's IRB Approval
- Data Collection Sheet
- Debriefing Script
- Device Information/Documentation
- Grant Proposal/Sub-Contract
- Human Subjects Training Certificate/Proof of Training
- Information Sheet/Brochure
- Interview/Focus Group Questions
- Investigator's Brochure
- Letter of Agreement/Cooperation
- IND Application Letter
- Package Insert
- Patient Diary Form
- Questionnaire/Survey
- Recruitment Material (e.g., flyers, ads, e-mail text)
- Safety Information (DSM Information)
- Scientific/PPC Review or Department Chair Review
- Sponsor's Protocol
- Sponsor's Protocol Amendment
- Study Design Chart/Table
- Other files associated with the protocol (most standard formats accepted: pdf, jpg, tiff, mp3, wmv, etc.)

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.



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Document Type	Document Name	Attached Date	Submitted Date
Bibliography	References	11/13/2013	12/18/2013
Human Subjects Training Certificate/Proof of Training	Yancey CITI (all reports)	12/19/2013	12/19/2013
Human Subjects Training Certificate/Proof of Training	Forinash CITI Certificate 5-13	12/19/2013	12/19/2013
Human Subjects Training Certificate/Proof of Training	Forinash CITI 5-2010	12/19/2013	12/19/2013
Human Subjects Training Certificate/Proof of Training	Forinash CITI 9-2010	12/19/2013	12/19/2013
Human Subjects Training Certificate/Proof of Training	CITI Hebel, Danielle	12/19/2013	12/19/2013
Package Insert	Wellbutrin	12/23/2013	02/21/2014
Package Insert	Nicotine patch	12/23/2013	02/21/2014
Other	Letter of cost	02/04/2014	02/21/2014
Other	Hebel Award Letter	03/11/2014	03/11/2014
Grant Proposal/Sub-Contract	ASHP_Grant_-_Smoking_10.18.2013 FINAL	03/12/2014	03/12/2014
Data Collection Sheet	Approved_Data Collection Sheet 2-2014	03/12/2014	03/12/2014
Other	Approved_Text Script for refills	03/12/2014	03/12/2014
Other	Approved_Smoking_Cessation_Text_Messages_4 (1)	03/12/2014	03/12/2014
Phone Script	Approved_Phone f-u script 1-14	03/12/2014	03/12/2014
Cooperating Institution's IRB Approval	2014-03 B Smoking Cessation Following Text Message Intervention in Pregnant Women APPROVAL	03/24/2014	03/31/2014
Data Collection Sheet	Approved_Data Collection Sheet 3-31-2014	04/07/2014	04/07/2014
Data Collection Sheet	Approved_Data Collection Sheet clean 4-17-2014 (2)	05/08/2014	05/08/2014
Cooperating Institution's IRB Approval	COP approval	05/12/2014	05/14/2014
Recruitment Material (e.g., flyers, ads, e-mail text)	Approved_Smoking_cessation_advertisement	08/19/2014	08/19/2014

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Human Subjects Training Certificate/Proof of Training	SSM CITI Biomedical Training Koerner	09/10/2014	09/10/2014
Human Subjects Training Certificate/Proof of Training	Inteso CITI	07/08/2015	07/13/2015

**Document Type** Bibliography  
**Attachment** References  
**Document Name** References

**Document Type** Human Subjects Training Certificate/Proof of Training  
**Attachment** Yancey CITI (all reports)  
**Document Name** Yancey CITI (all reports)

**Document Type** Human Subjects Training Certificate/Proof of Training  
**Attachment** Forinash CITI Certificate 5-13  
**Document Name** Forinash CITI Certificate 5-13

**Document Type** Human Subjects Training Certificate/Proof of Training  
**Attachment** Forinash CITI 5-2010  
**Document Name** Forinash CITI 5-2010

**Document Type** Human Subjects Training Certificate/Proof of Training  
**Attachment** Forinash CITI 9-2010  
**Document Name** Forinash CITI 9-2010

**Document Type** Human Subjects Training Certificate/Proof of Training  
**Attachment** CITI Hebel, Danielle  
**Document Name** CITI Hebel, Danielle

**Document Type** Package Insert  
**Attachment** Wellbutrin  
**Document Name** Wellbutrin

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<b>Document Type</b>	Package Insert
<b>Attachment</b>	Nicotine patch
<b>Document Name</b>	Nicotine patch
<b>Document Type</b>	Other
<b>Attachment</b>	Letter of cost
<b>Document Name</b>	Letter of cost
<b>Document Type</b>	Other
<b>Attachment</b>	Hebel Award Letter
<b>Document Name</b>	Hebel Award Letter
<b>Document Type</b>	Grant Proposal/Sub-Contract
<b>Attachment</b>	ASHP_Grant_-_Smoking_10.18.2013 FINAL
<b>Document Name</b>	ASHP_Grant_-_Smoking_10.18.2013 FINAL
<b>Document Type</b>	Data Collection Sheet
<b>Attachment</b>	Approved_Data_Collection_Sheet_2-2014
<b>Document Name</b>	Approved_Data Collection Sheet 2-2014
<b>Document Type</b>	Other
<b>Attachment</b>	Approved_Text_Script_for_refills
<b>Document Name</b>	Approved_Text Script for refills
<b>Document Type</b>	Other
<b>Attachment</b>	Approved_Smoking_Cessation_Text_Messages_4_(1)
<b>Document Name</b>	Approved_Smoking_Cessation_Text_Messages_4 (1)
<b>Document Type</b>	Phone Script
<b>Attachment</b>	Approved_Phone_f-u_script_1-14
<b>Document Name</b>	Approved_Phone f-u script 1-14
<b>Document Type</b>	Cooperating Institution's IRB Approval

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<b>Attachment</b>	2014-03 B Smoking Cessation Following Text Message Intervention in Pregnant Women APPROVAL
<b>Document Name</b>	2014-03 B Smoking Cessation Following Text Message Intervention in Pregnant Women APPROVAL
<b>Document Type</b>	Data Collection Sheet
<b>Attachment</b>	Approved_Data Collection Sheet 3-31-2014
<b>Document Name</b>	Approved_Data Collection Sheet 3-31-2014
<b>Document Type</b>	Data Collection Sheet
<b>Attachment</b>	Approved_Data_Collection_Sheet_clean_4-17-2014_(2)
<b>Document Name</b>	Approved_Data Collection Sheet clean 4-17-2014 (2)
<b>Document Type</b>	Cooperating Institution's IRB Approval
<b>Attachment</b>	COP approval
<b>Document Name</b>	COP approval
<b>Document Type</b>	Recruitment Material (e.g., flyers, ads, e-mail text)
<b>Attachment</b>	Approved_Smoking_cessation_advertisement
<b>Document Name</b>	Approved_Smoking_cessation_advertisement
<b>Document Type</b>	Human Subjects Training Certificate/Proof of Training
<b>Attachment</b>	SSM CITI Biomedical Training Koerner
<b>Document Name</b>	SSM CITI Biomedical Training Koerner
<b>Document Type</b>	Human Subjects Training Certificate/Proof of Training
<b>Attachment</b>	Inteso CITI
<b>Document Name</b>	Inteso CITI

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