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Randomized Test of Financial Incentives for Smoking Cessation Treatment Engagement among Adult Primary Care Patients

Protocol Number:

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Protocol Version History

Protocol Version	Version Date	Summary of Revisions Made	Rationale
1.0	03/27/2020	Initial version	
1.1	4/2/2020	Reduce # of experimental arms	Recruitment capacity
1.2	3/22/2020	Medicare & Medicaid exclusions	Federal prohibitions on financial incentives
2.0	9/8/2020	• Switch to ICTR REDCap Instance • added nicotine use questions to 3/6mo. follow up assessments • rewrote Aims to better conform w/ ClinicalTrails.gov requirements • Minor wording edits to assessments	• ICTR REDCap allows faster launch • nicotine use questions were noted across protocol but not included in follow-up instrument, • clarification of Aims required for CT.gov entry • adapt for CATI delivery
3.0	1/6/2021	Eliminate Contact Incentive and increase one arm of Treatment Engagement Incentive	Contact Incentive produced insufficient response

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1.0 STATEMENT OF LIST OF ABBREVIATIONS

CI	Contact Incentive
EHR	Electronic Health Record
GHC-SCW	Group Health Cooperative of South Central Wisconsin
HIPAA	Health Insurance Portability and Accountability Act
ICTR	Institute for Clinical and Translational Research
IRB	Institutional Review Board
NCI	National Cancer Institute
NIH	National Institutes of Health
NRT	Nicotine Replacement Therapy
PHI	Protected Health Information
PI	Principal Investigator
REDCap	Research Electronic Data Capture
SFTXT	SmokefreeTXT, the NCI text-message smoking cessation support intervention
TCOS	Tobacco Cessation Outreach Specialist
TEI	Treatment Engagement Incentive
UW-CTRI	University of Wisconsin Center for Tobacco Research and Intervention
WTQL	Wisconsin Tobacco Quit Line

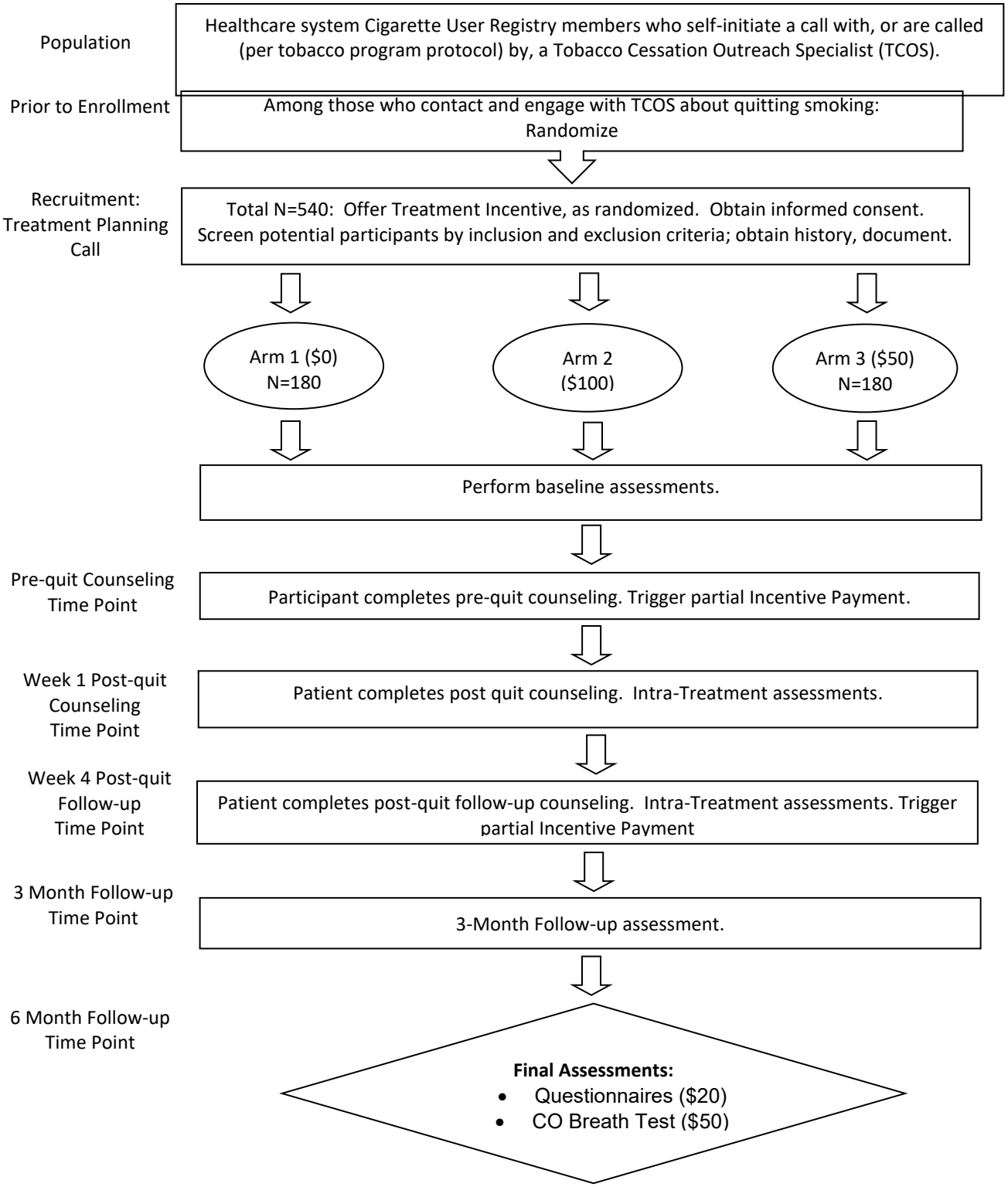
2.0 STUDY SUMMARY

2.1 Synopsis

Full Title	Randomized Test of Financial Incentives for Smoking Cessation Treatment Engagement Among A Healthcare System's Universal Primary Care Population
Short Title	[Financial Incentives for Smoking Cessation Treatment Engagement]
Protocol Number	[HS IRB 2020-0717]
ClinicalTrials.gov Identifier & Summary	[pending] [This study is being done to see if financial incentives increase the rate at which smokers engage in cessation treatment.]
Number of Site(s)	Approximately 6 clinical sites in the United States
Main Inclusion Criteria	• Adult members (patients) of participating healthcare system • Current smokers • English- or Spanish-speaking (able to complete questionnaires in English or Spanish over the phone)
Main Exclusion Criteria	• Prior participation in the study • Has a target quit smoking day within the past or next 30 days in the EHR • Medicare or non-BadgerCare Medicaid billable insurance
Objective(s)	<u>Primary Objective</u> • To determine the relations between treatment engagement financial incentive amounts offered and likelihood of patient engagement in smoking cessation treatment (defined as setting a target quit day and completing phone counseling). <u>Exploratory Objectives</u> • Conduct exploratory analyses on the effects of different incentive engagement amounts on biochemically confirmed point-prevalence abstinence 6 months post-quit-date, and determine whether incentive condition affects abstinence via effects on smoking treatment engagement (i.e., whether smoking treatment engagement mediates the relations between engagement incentive condition and 6-month smoking abstinence). • To determine the incremental cost-effectiveness of varying financial engagement incentives with regard to total program costs vs. usual care, net monetary benefit (NMB), cost per quit, and incremental cost-effectiveness ratios (ICERs), with the last determined with regard to cost of each additional smoker engaged in cessation treatment and each additional individual who quits smoking. • To determine the representativeness of smoking treatment reach and smoking abstinence effects of various engagement incentive amounts with regard to different groups of smokers: e.g., those low in socio-economic status, priority populations, different racial and ethnic groups.
Study Design	This is a randomized, active placebo-controlled, trial of the effectiveness of financial incentives for adults smokers to engage tobacco treatment.
Study Intervention	Adults meeting Cigarette User Registry criteria who call or are contacted by their healthcare system to discuss tobacco use will be randomized to $100, $50, or $0 incentive for

	participating in quit planning and quit counseling with a tobacco cessation specialist. Questionnaires will be completed at Week 1, Week 4, Month 3, and Month 6; exhaled breath CO measurements will confirm abstinence at 6 months.
Total Number of Subjects	A total of 540 subjects will be recruited from 6 primary care clinics of the participating healthcare system.
Study Population	Males and females aged 18 or above who are current cigarette smokers.
Statistical Methodology	An intention-to-treat analysis using logistic regression to contrast the likelihood of smoking treatment engagement/entry for the three incentive conditions.
Estimated Subject Duration	The duration of the study for each subject is approximately 28 weeks.
Estimated Enrollment Period & Study Duration	Study enrollment and follow-up will occur over 18 months with the total expected duration of the trial to be 48 months.

2.2 Schematic of Study Design



3.0 Significance

Research shows that evidence based cessation treatments such as telephone counseling and FDA-approved smoking cessation medications are effective; they increase abstinence rates significantly if smokers use them for a quit attempt. However, an important impediment to their population impact is that only a relatively small percentage of smokers participate in such treatments when offered (that is, smoking cessation treatments have low 'reach' in healthcare populations). Specifically, when offered smoking treatment perhaps only 20% or so of smokers agree to treatment referral, and then perhaps only 5-10% actually enter such treatment[1,2]. Previous research shows that providing financial incentives for participating in smoking cessation interventions increases both treatment participation and abstinence rates[3-6]. However, much of that research was conducted in Medicaid populations and did not occur in a healthcare setting and with a patient population. Moreover, some of this research used large incentives for treatment engagement (e.g., Baker et al., 2018; Fraser et al., 2017, Volpp et al., 2016)[4,5,7] that may be difficult for health systems or insurers to maintain. Thus, at present, little is known about the effectiveness of a treatment-engagement incentive program that is offered to all smokers in a healthcare system when the incentives are of a magnitude that would make the program attractive to, and affordable for, healthcare systems or insurers. This study is designed to test the hypothesis that modest incentives offered to all smokers in a healthcare system will increase both participation in smoking cessation treatment and resulting abstinence rates. The incentive program will involve an 'engagement incentive' that is intended to increase patients' engagement in smoking treatment when it is offered by the tobacco cessation outreach specialist (TCOS). Further, in an effort to increase the reach of smoking treatment, all smokers listed on the healthcare system's smoker registry will be alerted about the availability of incentives during routine TCOS telephone outreach provided as standard practice 1) within 2 weeks of each primary care encounter ('recent visit call' and 2) at least annually to those without a primary care or TCOS encounter in the prior year ('annual call'); thus, the offer of treatment will not depend on smokers' making a healthcare visit. If successful, this incentive-based reach program could be disseminated to reduce the considerable financial and personal costs associated with smoking-related disease.

4.0 Goals/Aims

4.1 Goals This project will apply a three-armed randomized block design to identify whether financial incentives are effective in increasing acceptance of, and engagement in, smoking intervention services as well as smoking cessation amongst Group Health Cooperative (GHC-SCW) patients who smoke. All members of the GHC-SCW Cigarette Users Registry (i.e., individuals who the health system believes are smokers, the 'Registry') at the time of implementation will be eligible to participate. Smokers who speak with the TCOS staff when called for standard care management outreach following a recent primary care visit or during an annual outreach call and listen to the description of smoking treatments will be randomized to receive one of three incentive amounts ($0, $100, & $50) for continuing treatment planning, establishing a target quit date and completing two telephone counseling sessions. Participants will be told about the size of their incentive, which in theory will increase their likelihood of engaging in smoking treatment and therefore, quitting smoking successfully. For the non-$0 incentive groups, ½ the total value will be apportioned for completion of each a Pre-quit

counseling call and a Week 4 counseling call. Participants (N=540) will be recruited in up to 6 primary care clinics with randomization blocked on clinic so that roughly 1/3 of all enrollees in a given clinic will be in each of the treatment use incentive conditions to avoid incentive by clinic confounds. Sex and minority status will also be used as blocking factors to limit confounding the impact of the incentive on these demographic characteristics.

4.2 Aims

Primary Aim

1. To determine the relations between treatment engagement financial incentive amounts offered and likelihood of patient engagement in smoking cessation treatment.

    a. Primary outcome measure: Patient engagement in smoking cessation treatment (defined as setting a TQD and completing the two phone counseling calls).

Exploratory Aims

1. To determine the incremental cost-effectiveness of the different financial engagement incentive amounts with regard to total program costs vs. usual care, net monetary benefit (NMB), cost per quit, and incremental cost-effectiveness ratios (ICERs), with the last determined with regard to cost of additional smoker recruited and each additional individual who quits smoking.
2. To determine the representativeness of smoking treatment reach and smoking abstinence outcomes generated by the various engagement incentive amounts with regard to different groups of smokers: e.g., those low in socio-economic status, priority populations, different racial and ethnic groups.
3. Conduct exploratory analyses on the effects of the different incentive engagement amounts on biochemically confirmed point-prevalence 6-month abstinence, and determine whether incentive condition affects abstinence via effects on smoking treatment engagement (i.e., whether smoking treatment engagement mediates the relations between different engagement incentive conditions and 6-month smoking abstinence).

5.0 Study Design

Design Overview. In this randomized controlled trial, each patient of participating GHC-SCW primary care clinics who is listed in the Cigarette User Registry receiving standard telephone contact from their GHC-SCW TCOS to discuss tobacco use treatment options will be reminded of GHC-SCW's commitment to helping them improve their health, advised to quit smoking, offered support to quit smoking, recruited, screened, consented, and randomized over the phone to one of three conditions of financial engagement incentives ($0, $100, $50). Smokers unwilling to participate in the incentivized treatment program will be offered entry into the existing GHC-SCW standard smoking cessation program. Patients participating in the research study will also receive smoking treatment via the existing GHC-SCW standard smoking cessation program. Participants in the research study will be told that they may receive a

treatment engagement incentive, with the amount consistent with their randomized incentive condition; receipt of their assigned incentive amount is dependent upon their setting a quit date and completing two smoking cessation treatment counseling contacts. The smoking cessation treatment includes medication and 3 quit smoking counseling calls scheduled to occur after the recruitment contact call, which is the standard smoking cessation program available to all GHC-SCW patients. This program entails a brief counseling call a week (typically 5-7 days) Pre-quit, i.e. before the patient's target quit date (TQD), approximately 5-7 days following the TQD (Week 1), and about one month following the TQD (Week 4). Research participants will be asked to complete brief (3 to 5 minute) assessments during each standard care smoking treatment counseling call by GHC-SCW, plus 15-25-minute research study phone interviews 3- and 6--months post-TQD for study purposes. Those claiming abstinence at the 6-month post-TQD phone interview will be asked to return to their primary care clinic to complete breath, urine, and/or saliva testing to verify abstinence from combustible tobacco. This will entail providing breath samples for carbon monoxide testing and/or a urine or saliva sample for immediate cotinine testing (no samples will be stored). Participants may also be asked to collect a saliva sample at home and return it in the mail if they do not attend a biochemical verification visit.

6.0 Subject Selection

6.1 Subject Identification

Up to 540 adult participants will be recruited from the 6 primary care clinics of the GHC-SCW healthcare system over 6-12 months. All patients who meet criteria for the existing GHC-SCW Cigarette Use Registry who do not have an existing Target Quit Date ±30 days and who either are currently contacted by the TCOS following each primary care encounter or are identified as not having had a primary care encounter in prior 365 days. During this outreach TCOS will provide the incentive offer and recruit for participation. GHC-SCW also currently provides quarterly bulk communications promoting the availability of tobacco use treatment through their TCOS. Patients who initiate contact with a TCOS in response to these messages will also be offered enrollment. TCOS are healthcare system employees nationally certified in tobacco treatment and will have completed all relevant human subjects research, HIPAA, and good clinical practice trainings to enable them to become members of the study team for the performance of screening, consenting, randomization, phone-based assessments, and other research activities, as required. Patients can participate in the incentive research program only once but can use the GHC-SCW standard smoking treatment program repeatedly.

The TCOS will explain that the healthcare system is reaching out to all smokers to offer support and resources to help them protect their health. The TCOS will trigger the randomization assignment, advise all patients who smoke to quit, let them know that s/he can offer help in quitting, and ask if patients are interested in quitting within the next 30 days. If the patient is assigned to either the $100 or $50 incentive, the TCOS will inform the patient that they can earn that incentive for setting a quit plan within the next 30 days and completing two smoking treatment counseling calls. If patients are in the $0 incentive condition they will be offered the opportunity to enter the smoking cessation treatment program with no offer of a financial incentive for treatment engagement, which is consistent with usual care. If patients agree to receive smoking treatment, they will be asked brief screening questions.

6.2 Inclusion/Exclusion criteria

Inclusion criteria

- Age > 17 years.
- On Cigarette User Registry at a participating clinic
- Able to speak English or Spanish

Exclusion criteria Activated healthcare power of attorney or cognitive impairment that would preclude informed consent.

- Existing target quit date ±30 days from date of call to TCOS
- Current billable insurance status in EHR of Medicare or non-BadgerCare Medicaid
- Prior screening for Treatment Engagement incentive enrollment

Those who agree to and pass screening for the inclusion/exclusion criteria for study participation will be asked to complete an oral consent and HIPAA authorization process. Those who decline the screening invitation, do not meet eligibility criteria, or do not provide oral consent for study participation will be advised to quit smoking and offered standard smoking cessation treatment.

Those who consent to the study will then be asked to complete a baseline assessment and will set a quit date with TCOS, which will determine the times of the therapy contacts offered as part of the GHC-SCW standard smoking cessation treatment.

6.3 Vulnerable Populations

Because we seek to evaluate interventions that will promote use of evidence-based treatment, and thereby abstinence from smoking, from the full range of adult daily smokers who receive healthcare services from the GHC-SCW healthcare system, we will not exclude members of vulnerable populations, including pregnant women (for whom quitting smoking is an important goal for the health of both mother and child) or those on parole or probation (this will not be assessed, as it is not directly relevant to the study and does not materially alter the risk to benefit ratio of participation). Individuals who are in institutional living situations (e.g., in assisted living facilities) will also be eligible, if they are adults, smoke daily, are enrolled at a GHC-SCW primary care clinic, and are considered competent to make healthcare decisions according to existing healthcare system protocols and procedures. TCOS will be trained to check this information and to seek only oral consent from those capable of providing such consent. Excluding members of these vulnerable populations is not warranted for their protection and would instead unjustly prevent their involvement in a minimal-risk program offering benefit (information about the opportunity to connect with evidence-based smoking treatment at no personal cost, apart from telephone charges where applicable and standard GHC-SCW smoking cessation clinical treatment). In addition, while the study does not target incarcerated individuals, some participants may be incarcerated during the period of study involvement. All study outreach, treatment provision, and assessment will be suspended during a participant's period of incarceration.

None of these vulnerable populations will be specifically targeted in recruitment. The proposed reach interventions, assessments, and compensation schedule should pose no more risk for pregnant women, those on parole or probation, or those in institutionalized settings than for the general population, as study procedures confer minimal risk, are informational in nature, and are entirely voluntary. As part of the normal delivery of the GHC-SCW smoking treatment program, if a patient has contraindications to the use of smoking medication (e.g., pregnancy), that patient will not be offered such medication as part of their treatment.

In addition to the engagement incentives, $20 for completing a telephone survey 6 months after their original Target Quit Date and $50 in compensation will be offered to patients for completing the 6-month post-enrollment visit for biochemical validation of abstinence from smoking. This payment for completing this important research assessment will be available to all enrolled participants, regardless of assigned experimental condition.

6.4 Consent & Enrollment

GHC-SCW TCOS staff will be responsible for program implementation and data documentation (using existing EHR and administrative data fields) except for 3- and 6-month Follow Up survey collection completed by the research staff. Only limited patient and systems data will be shared with the research team documenting which patients were called as standard practice but declined study participation.

All patients who agree to the study offer – tailored to their assigned Treatment Engagement Incentive value (Attachment B: Invite script), and pass the inclusion and exclusion criteria for Treatment Engagement Incentive study participation will be read an oral consent script by a healthcare system TCOS (see uploaded Recruitment Call script). The consent script read to participants over the phone conveys the key points regarding study procedures; risks; and participant rights, protections, and benefits, and does so in accessible language (assessed for reading level). The consent will inform patients that some monetary payments may be offered as part of the study for engaging in study components, including $20 for completing a telephone survey 6 months after their original Target Quit Date and $50 for those who report smoking abstinence at 6 months who complete an in-person breath CO breath test, urine, or saliva test, but the [incentive] amounts available will not be disclosed (so that some patients will not refuse further engagement due to disappointment with their incentive amount). Prospective participants will be given an opportunity to ask questions and raise concerns during this process, which will be addressed prior to seeking oral consent. Informed consent for study participation will be formally documented electronically in the UW-ICTR REDCap instance study database. Following enrollment for those who consent, TCOS staff will send out a letter in hard copy to the participant at the address provided (see uploaded Study Information Sheet). This letter will remind the participant of study procedures and will include a detailed study information enclosure containing all required elements of informed consent and HIPAA authorization.

Those randomly assigned to either the $100 or $50 incentive conditions will be reminded that they can earn the incentive by completing two counseling calls with the TCOS but they will also be encouraged to attend all three standard calls. GHC-SCW provides smoking cessation treatments at no or almost no cost (e.g., medication copays) for all members targeted by this study.

Data available to researchers on participants enrolled will include: a) data collected in the course of usual clinical care extracted from the EHR, b) research assessments conducted over the phone documented in REDCap or other research database, and c) the one-time carbon monoxide breath sample captured in-person using a Bedfont Breathalyzer unit, or, alternatively urine samples collected in clinic, or saliva samples collected at home or in clinic.

Given the remote nature of the outreach and because we want to reduce burden (e.g., travel) for participants, an oral consent process seems in our view to be most beneficial to participants in this minimal risk study. Moreover, this approach will likely protect the external validity of the findings by closely resembling steps used in real-world wellness and prevention interventions. Collecting consent over the phone also reduces the risk that we will inadvertently bias the sample toward the most motivated, stable, or affluent members of the target population as might occur with face-to-face or mailed consent processes. Mailing a written consent form and waiting for this to be returned would likely result in meaningfully fewer patients following through and taking advantage of this incentivized smoking treatment opportunity than would occur with oral consent; this would not only reduce patient benefit but would yield data that are less representative of the effects of incentive interventions in real world healthcare systems (e.g., by over-selecting those who are more motivated), which could affect both treatment engagement rates and success rates of the standard smoking treatment.

For these reasons, we also propose to use an altered HIPAA authorization because it would be impracticable to obtain authorization with all elements required under the HIPAA Privacy Rule over the phone. We also seek to waive some of the required elements of consent and HIPAA authorization over the phone in order to reduce participant burden and to enhance comprehension of the material read to participants, without omitting any key information pertinent to risks, rights, or protections. Consent and HIPAA authorization over the phone will cover the collection of data from the electronic health record for research purposes. The mailed Study Information Sheet that will follow the telephone enrollment and oral consent process will include all required elements of consent and HIPAA authorization (including a statement regarding how long permission to use the PHI will last, how to withdraw permission for PHI use, and the mandatory statement that the PHI could be redisclosed without subjects' permission in the consent/authorization and enrollment process). The Study Information Sheet also details how to withdraw from the study and revoke authorization to use PHI, without penalty or punishment. The mailed Study Information Sheet will provide a phone number for participants to call should they have questions.

The TCOS will ask if the participant gives the study permission to stay in touch with them and send them reminders about upcoming study contacts during the study via email and/or text message. The TCOS will remind them that email and text messaging are generally not a secure way to communicate about their health as there are many ways for unauthorized users to access email and text messages. The TCOS will also inform them that they do not have to provide their email address or text message number to participate in this study.

With regard to compensation and incentives, the Consent Script and mailed Study Information Sheet will make clear distinctions between compensation for completing the 6-month follow-up assessment and smoking abstinence biochemical confirmation (available in all conditions), and incentives for treatment engagement (available to about 2/3 of participants). This is important for

the sake of transparency and to ensure that incentive effects are not masked by misattribution of compensation as an incentive by participants.

6.5 Randomization

Randomization will occur during the contact call immediately after patients have been told of their smoking treatment options. The TCOS will then use randomization tables developed by UW-CTRI to randomize potential enrollees, blocked by clinic, sex, and race, into 1 of 3 engagement incentive conditions ($0, $100, or $50). After randomization, patients will be offered smoking treatment with the incentive for treatment entry (engagement) to which they had been randomized. This offer will require the participant to agree to set a stop-smoking quit date within the next 30 days. This offer will occur prior to the patient's provision of consent to participate in research. The patient must be offered the incentive up-front to see if this increases their treatment engagement (which necessarily includes agreement to it/consent); offering the incentive after agreeing to participate in treatment would not reveal the effects of the incentive on spurring engagement. Thus, we are interested in the effects of incentives on both agreement to enter treatment and actual likelihood of engaging in it. If a patient decides to accept the treatment offer, s/he will be consented and will set a target quit date with the TCOS (within 1 month of the contact phone call). For patients who are unwilling to set a stop-smoking quit date within the next 30 days the TCOS will describe all stop-smoking treatment options that are available as part of usual care and encourage the patient to call the TCOS back when ready to set a quit date within 30 days. For patients who decline the research study, the TCOS will describe all stop-smoking treatment options that are available as part of usual care and provide quit smoking treatment as usual.

7.0 Study Treatments and Experimental Conditions

Smoking cessation treatments will not be experimentally manipulated or varied as a function of research participation. Participants and non-participants will be treated per standard clinical protocols for tobacco use. The experimental conditions (i.e., the incentives) in the study are intended to effect smoker *engagement* in treatment as offered by healthcare system personnel. The primary differences between research study participation and usual care with regard to smoking treatment are: 1) the consent process, 2) randomization to treatment engagement incentive condition and provision of such incentive, 3) follow-up to determine patient smoking status. Importantly, actual smoking cessation treatments (counseling and medications, the existing GHC-SCW standard of care) will be identical for both those who chose to participate in the study and those who do not (Figure 2).

7.1 Incentives In 2 of our recent studies[4,5], incentive-driven increases in counseling use mediated incentive effects on abstinence in Medicaid-insured smokers. Given the significant savings associated with smoking cessation[8], modest incentives to engage in treatment may well be cost-effective if they increase quitting. Modest incentives ($25 or $50) also improve attendance at primary care visits[9]. Thus, evidence supports modest, utilization-contingent incentives for use of both smoking cessation and primary care treatment. The proposed project

will evaluate the effects of incentives of varying magnitude for smoking treatment engagement (rather than achieving abstinence) in primary care.

To identify an especially effective incentive amount, three different incentive value conditions will be evaluated (0, $100, and $50). The incentive will be tied to readily observable *initiation* of treatment (i.e., setting a target quit date within 30 days on a call with a TCOS and actually engaging in the first phone smoking cessation counseling session) and *follow through* with treatment (i.e., engaging in the Week 4 counseling session). The two positive (non 0) incentive tiers were selected based on the results of earlier work that used $30 incentives to improve counseling session attendance, and through this pathway, abstinence rates among low-income smokers. Participants will be paid by mailed check or gift card.

Figure 2. GHC-SCW Healthcare System Standard Tobacco Treatment Program

All patients on the Cigarette Users Registry receive:

- Quarterly Bulk Outreach via postal mail and MyChart promoting the tobacco treatment program services
- Care Management telephonic outreach calls by TCOS following each primary care visit and no less than once per year.

Patients are offered ongoing access to resources but expected to set a target quit date (TQD) to focus cessation planning and arrange medications. Elements include:

- 3 brief telephone counseling sessions with a Certified Tobacco Treatment Specialist (TCOS)
  - 3-5 days pre-,
  - 5-7 days post- (Week 1),
  - 4 weeks post-TQD (Week 4)
- Smoking cessation pharmacotherapy including combination NRT, varenicline, or any of 7 FDA approved medications.
- Integrated referrals to:
  - primary care physician
  - WI Tobacco Quit Line
  - SmokefreeTXT program
- Weekly facilitated Tobacco Use Support Group
- Ongoing TCOS support through MyChart (EHR patient portal) and phone

8.0 Detailed Study Procedures: Recruitment and Assessments

8.1 Recruitment As noted in the enrollment flow diagram in Attachment A, recruitment will occur over the phone (in the Treatment Planning call) following a patient response to standard TCOS outreach. TCOS as per their current GHC-SCW usual care protocol will provide callers with advice to quit and an overview of cessation treatment options. The TCOS will assess the smoker's readiness to quit in the next 30 days as per usual care. In accordance with randomized condition, the TCOS will offer the appropriate intervention incentive per the Invite Script (Attachment B). For those who tell the TCOS that they are ready to quit within 30 days, the TCOS will offer treatment enrollment and provide standard care per the existing tobacco treatment program of the GHC-SCW healthcare system (e.g., setting quit date, arranging timing of treatment contacts: See Figure 2.).

The TCOS will be trained to present information about the Treatment Engagement Incentive offer, assessing eligibility, informed consent, and research assessment processes in a standardized manner.

UW-CTRI personnel will be responsible for: conducting telephone follow-up interviews 3- and 6-months post-TQD and meeting with patients to verify claimed abstinence 6-months post-TQD via biochemical testing (breath CO, urine, and/or saliva testing without biobanking). The

biochemical testing visit will be conducted at UW-CTRI or a practical location of the participant's choosing.

Personnel from both the healthcare system and UW-CTRI will therefore have contact with study participants and/or their data. Coordination of all activities will be led by UW-CTRI and UW-CTRI will perform all data analyses. All data transmissions to and from UW-CTRI will occur via secure, HIPAA-compliant means via capture in REDCap or SFTP or secure Box file transfers.

8.2 Assessment Plan

Baseline assessment (See uploaded Baseline Assessment and uploaded List of EHR Data to Be Extracted). At enrollment, TCOS will assess tobacco use history and smoking cessation history, dependence, motivation and self-efficacy related to quitting smoking, attitudes about and beliefs regarding smoking cessation treatments, and education. EHR data regarding age, sex, race, ethnicity, contact information, communication preferences, and documentation regarding social determinants of health (e.g., food insecurity, housing insecurity, financial strain) educational attainment will be obtained. Chronic medical conditions and healthcare utilization over the past year will be extracted from EHR data, as well.

Intra-treatment assessments (See uploaded Intra-Treatment Assessment). At the 3 standard treatment telephone counseling calls, TCOS will assess daily smoking since last contact, counseling engagement, withdrawal, self-efficacy, and use of all nicotine/tobacco products.

Follow-up assessments (See uploaded Follow-up Assessment). UW-CTRI staff will conduct 15-25-minute follow-up interviews 3- and 6-months after study enrollment to assess past 7-day smoking, use of smoking cessation treatments, use of all nicotine/tobacco products, brief demographic characteristics, and treatment satisfaction. Participants will receive $20 for participating in the 6-month follow-up interview and $50 for attending the 6-month biochemical confirmation visit at 6 months.

To enhance follow-up interview and visit completion rates, participants will be texted, mailed, sent MyChart messages or sent automated phone calls (depending on their communication preferences as noted in the EHR and during enrollment) to remind them of follow-ups.

Although this program will evaluate interventions delivered by healthcare system personnel (Tobacco Cessation Outreach Specialists), follow-up data collection procedures and collation of data from multiple sources/sites necessary for thorough program evaluation are the responsibility of the UW-CTRI study investigators. To achieve the study aims, UW-CTRI investigators require access to identifiable patient data on all enrolled participants. At UW-CTRI, all study data will be stored in a HIPAA-compliant and secure manner on Department of Medicine servers with UW-CTRI-controlled password access. Staff trained in human subjects research and HIPAA compliance will link these datasets using a random subject identifier and will then de-identify the data for analyses.

9.0 Analysis Plan

9.1. Data Sources

Data will come from EHR records extracted by healthcare personnel and from research records of post-enrollment and follow-up assessments.

9.2 Subject Population Initial Analyses Descriptive statistics will be used to characterize the participants randomized to all the incentive conditions and these data will be compared with the characteristics of all patients who are listed on the Cigarette User Registry and also for just those on the Registry who do not participate in the research program. The data from these patients will be compared with the data from research participants to assess the representativeness of the sample enrolled in the study.

9.3 Planned Analysis

Primary Aim

- To determine the relations between treatment engagement financial incentive amounts offered and likelihood of patient engagement in smoking cessation treatment (defined as setting a TQD and completing the two phone counseling calls (Pre-quit + Week 4).

Primary analysis. The primary outcome measure will be patient engagement in smoking cessation treatment (defined as setting a TQD and the number of completed phone counseling contacts). We will determine the percentage of those in each incentive condition who engage in smoking cessation treatment. We will use logistic regression analyses to contrast the likelihood of engaging in any smoking treatment (vs none) for the three incentive conditions (0 incentive, $100, and $50), with the 0 incentive condition being the reference condition in the primary analysis. We will also examine incentive condition effects on the number of scheduled counseling visits completed (0-3 visits) via ordinal logistic regression.

Additional exploratory analyses related to the primary aim. In additional exploratory analyses, we will determine the percentage of all GHC patients who are contacted by the TCOS and offered the Treatment Engagement Incentive. We will separately determine the percentage of those in each incentive condition who agree to set a TQD. We will use logistic regression analyses to contrast the likelihood of engaging in smoking treatment for the three incentive conditions, with (as mentioned above) the 0 incentive condition being the reference condition in the primary analysis, followed by comparison of the $100 and $50 conditions both with the reference condition and with one another. The primary analyses will not use covariates. Follow-up analyses will use the patient's home clinic and the patient's TCOS as covariates. Furthermore, using logistic regression, we will examine the relation between incentive condition and use of pharmacotherapy as the outcome (with medication orders and pick-up entered in the EHR and/or billing data).

Exploratory Aims

- Conduct exploratory analyses on the effects of the different incentive engagement amounts on biochemically confirmed point-prevalence 6-month abstinence and determine whether incentive conditions affect abstinence via their effects on smoking treatment engagement (i.e., whether smoking treatment engagement mediates the relations between different engagement incentive conditions and 6-month smoking abstinence).

Analysis. Logistic regression will be used to determine whether the different incentive levels ($0, $100, $50) produce effects on 6-month, biochemically confirmed point prevalence smoking

abstinence using the strategy described for Primary Aim. Dummy coding will be used to compare: 1) each positive incentive condition with the 0 incentive condition, and 2) the two positive incentive conditions will be compared with one another. The primary analyses will not use covariates. Secondary models will adjust for the patient's home clinic and the patient's TCOS as covariates, Gender, race, cigarettes smoked/day will be added as covariates in later analyses. Mediational analyses will be done using incentive condition as the independent variable, engagement data as mediators (attendance at the initial treatment contact, number of counseling contacts made, or use of smoking medication). The outcome variable will be smoking abstinence at 3 months (self-report only) and 6 months (biochemically confirmed self-report).

- To determine the incremental cost-effectiveness of the different financial engagement incentive amounts with regard to total program costs vs. usual care, net monetary benefit (NMB), cost per quit, and incremental cost-effectiveness ratios (ICERs), with the last determined with regard to cost of additional smoker engaged in treatment and each additional individual who quits smoking.

Analysis. Cost data will come from: healthcare system costs in terms of outreach communications, TCOS time (related to outreach and counseling efforts), implementation costs, incentive costs, and medication expenditures (including related physician screening when it occurs). We will use methods recommended by the US Panel on Cost-Effectiveness in Health and Medicine[10] and consistent with our prior research. We will measure costs from a societal perspective using data on smoking cessation benefits from publicly available Medicare and Medicaid reimbursement rates. Cost estimates will be converted to a common year and QALYs will be computed, using a rate of 3% to discount future outcomes and costs to present value. We will also conduct probabilistic sensitivity analyses to account for uncertainty. We will determine net monetary benefit (NMB), cost per quit (using 6 month abstinence rates), and incremental cost-effectiveness ratios (ICERs)[11]. The components of NMB will be the added costs of the various incentive levels and the monetized value of the QALYs added by the treatments. Total intervention and implementation costs (including outreach and added TCOS time for intervention, implementation, and incentives) will be compared to program costs of the usual care approach to tobacco use (the TCOS intervention program prior to the incentive study implementation).

- To determine the representativeness of smoking treatment reach and smoking abstinence outcomes generated by the various engagement incentive amounts with regard to different groups of smokers: e.g., those low in socio-economic status, priority populations, different racial and ethnic groups.

Analysis. We will extract data from the EHR to characterize the healthcare system population of patients who smoke with regard to such factors as: gender, race, ethnicity, insurance mix. Such person factors will be related to the likelihood that the patient: responds to TCOS outreach, agrees to accept smoking treatment (agrees to a TQD and completes a counseling call), completes up to 3 counseling calls, picks up smoking medications, and achieves long-term abstinence. Logistic regression will be used to examine the likelihood that different person factors are significantly related to the various outcomes under the different incentive levels.

9.4 Power

This study is powered to detect a 12 percentage point difference in treatment engagement rates (defined as setting a TQD and completing 2 treatment phone counseling contacts) as a function of incentive amount. We believe that this rate is both feasible and of public health significance. We anticipate that the 0 incentive condition will have an engagement rate of about 15%. Since the rate of smoking treatment engagement is generally only about 5-7% in studies where incentives are not used we believe a 15% rate is conservative. We anticipate increased engagement in the control condition, relative to these earlier studies, because we believe it will be increased by TCOS contact and the opportunity to set a quit date on the contact call. We believe that a 12 percentage point increase above the 15% rate (to 27%) would be of public health significance. A total of 180 participants per group are needed to have power of .80 with alpha = .05 in a two-tailed test. This would translate into a study N = 540 with 180/condition for the comparison of each positive incentive condition vs the control condition. We make no a priori prediction about whether the $100 incentive condition will increase engagement relative to the $50 condition, but we certainly believe it will increase engagement relative to the 0 incentive condition. . Therefore, we propose an overall N=540.

While engagement is the principal outcome of this research we nevertheless have determined the effect size (increment in percent abstinent) we would need to have adequate power to detect difference in abstinence rates, as well. We anticipate that the $0 incentive condition will produce abstinence in 15% of those who contact the TCOS. With n=180/condition, we will have power=.80 to detect at least an 11 percentage point increase in abstinence above the 15% base rate in a 2-tailed test at alpha .05.

10.0 Human Subjects Protections and Data Sharing

10.1 Potential Benefits to Subjects and Society

Every participant in the study will be given information about ways to access evidence-based smoking cessation treatment to help them stop smoking and will be given access to that treatment within their healthcare system subject to limits and copays based on insurance coverage. One possible direct personal cost could be from telephone charges for telephone-delivered care such as cessation counseling and care management. Although smokers could access this care outside of the study, we know that only about 1-2% of smokers use a quit line and only about 5% use both medication and counseling. As such, the proposed study will offer all participants the benefit of information about treatment options and a low-barrier method of initiating treatment (i.e., by phone).

The proposed research also has the potential to benefit other smokers by identifying an effective population health incentive intervention that expands the reach of existing treatments with a feasible, cost-effective, and potentially sustainable approach in primary care settings. This work has the potential to accelerate the translation of clinical research on smoking interventions into healthcare practice and thereby reduce morbidity and mortality associated with smoking.

To promote public access to the results of this research, and thus its potential benefits, the study will be registered as a clinical trial at ClinicalTrials.gov, with information about the study purpose, experimental design, outcomes, and analyses available to the general public (with results posted within one year of study closing, as required).

10.2 Potential Risks to subjects

This project poses minimal risk to participants, as it entails only limited data collection solely for research purposes (up to 2 phone assessments with one possible 5-minute visit over 6 months for all enrollees and a modest (non-coercive) incentive to use standard care resources that are already available and consistent with FDA guidelines

The chief risks involved are loss of privacy and breach of confidentiality. Although we will take several steps to protect participant privacy, we cannot guarantee that patients may not experience an invasion of privacy. Some patients may perceive outreach letters from the health system as violating privacy, for example. Likewise, we cannot guarantee the confidentiality of the information collected directly from participants. Although we will not collect sensitive data directly, some data (i.e., substance use disorder diagnoses) may be included in limited data extracted EHR data.

The outreach message and motivational support given to participants in this project are unlikely to induce psychological distress, as they will be positive in tone and will focus on resources available to participants to support their efforts to change. Providing breath samples for carbon monoxide and/or providing saliva or urine for cotinine testing carries minimal risk, as these are minimally invasive procedures.

It is important to note that all patients will have access to evidence-based smoking cessation treatment at no or low cost (through their TCOS or primary care provider, subject to limits and copays based on insurance coverage and/or a quit line that offers evidence-based cessation treatment no cost to callers) and that receiving such treatment is not contingent on consenting to this study. It is also important to note that all patients will have the ability to decline or withdraw from the study and any study activities at any time.

10.3 Risks Minimization Plan.

To protect against breach of confidentiality or violations of privacy, we will ensure that data are stored on secure, encrypted servers at all participating sites, and that transfer of data between clinics and the UW-CTRI research team are conducted via HIPAA-compliant means. Communication with patients via the MyChart patient portal will likewise be conducted in HIPAA-compliant ways that conform to healthcare system standards. A unique study ID will be used to store all data on individual participants and information linking that study ID to participant identifying information will be maintained by the data manager. Data being used for analysis will be identified with the study ID only. Participant contact information will only be available to study staff having direct contact with participants. Data will be stripped of direct identifiers (limited datasets) or completely de-identified prior to sharing with others outside the IRB-approved research team.

In the course of the study participants may reveal important clinical information to their TCOS (tobacco cessation outreach specialist) regarding a serious health issue or change, the TCOS, who will be an employee of the healthcare system, will be able to communicate directly with the patient’s primary care team (e.g., if a patient reports that they are coughing up blood) via the EHR and will advise the patient to seek care from their care team or emergency care, as appropriate.

Routine adverse event assessment will not occur in this study, except in the context of smoking cessation treatment episodes, given the minimal and informational nature of the health system reach interventions and research assessments. Significant adverse events that occur during smoking cessation treatment will be gathered by the TCOS as a part of the patient's standard smoking cessation care. AE's will not be gathered by research staff. If a patient reports a concern AE or health related event to a research staff member, the patient will be encouraged to immediately seek medical attention from the participating healthcare system.

10.4 Risk/Benefit Analysis

This study carries minimal risk. The financial incentives to be deployed pose no risk above and beyond standard treatment and are too small to be coercive. No information about illegal behavior will be collected by research staff or entered into research data bases. The risk of someone's identity becoming known to unauthorized persons is low. This risk is outweighed by the benefits of quitting smoking for any individual, and the benefit to society of having fewer people use tobacco products. This research has the potential to benefit smokers in the future by helping to identify optimal financial incentive levels to promote use of smoking cessation treatments for broader dissemination. Therefore, the potential gain in knowledge regarding engagement incentives associated with the proposed study outweigh the risks of participation.

10.5 Unanticipated Problems or Complications

The Principal Investigator (PI) will be responsible for routinely monitoring study progress. UW-CTRI has a quality assurance monitoring protocol and team in place and will alert the study PI to significant problems that arise. Any data safety concerns will be reported to the PI immediately and addressed. We will report any unanticipated problems to the IRB according to posted guidelines. A full data safety and monitoring plan is included at the end of this protocol.

10.6 Privacy Precautions and Protections

Collection of sensitive information about subjects will be limited to the amount necessary to achieve the aims of the research. Participants will not be asked to disclose any information about illegal behavior.

10.7 Unauthorized Use or Disclosure Precautions and Plan

Participant study data will be collected by TCOS and UW-CTRI research personnel through the UW-ICTR instance of REDCap and will be stored on secure, password protected servers. Data will be accessible only to assigned study staff for their study function; computer workstations will be password-protected, and thus secured from unauthorized use. GHC-SCW healthcare system will transmit identifying information to UW-CTRI via secure, HIPAA compliant means (either a secure FTP site or a secure interface to the EHR).

During the active phase of the study, required patient identifying data will be stored in REDCap and linked to all study data via a study identifier (i.e., to guide randomization, phone calls, and assessments). PHI will be made inaccessible as soon as the study has been completed. Confidentiality of participant data and information will be accomplished by using participant numbers as unique identifiers, allowing us to keep participant data separate from identifying information. At UW-CTRI, data generated through study participation and data obtained from the EHR (with patient consent) and UW-ICTR instance REDCap will be incorporated into a UW-

CTRI analytical database and securely stored under protections and procedures consistent with the guidelines and regulations of the UW School of Medicine and Public Health (UW-SMPH). Outside access is available only via an encrypted connection to the Department of Medicine Citrix server located at the UW Clinical Science Center in Madison. The servers at the UW-CTRI Madison office are physically secured in a locked room. Data backups are created nightly and stored in a locked safe. Significant safeguards have been implemented to protect data including virus and adware protection, firewall, access controls and encryption when appropriate such as wireless and remote access. All UW-CTRI staff members have completed HIPAA and human subjects training and are aware of the sensitivity of study-related data. The study team has a Certificate of Confidentiality from the National Institutes of Health. The UW SMPH has developed school-wide data security policies and procedures. UW-CTRI data security policies and procedures conform to those of the SMPH. UW-CTRI will use the UW-ICTR instance of REDCap that supports audit trails such as access, change logging, and more sophisticated access control for managing and tracking user access privileges. No publications or presentations resulting from this research program will contain any identifying information about individual participants. Following cleaning and verification of data at the conclusion of the study, all research data will be placed in a de-identified data set at UW-CTRI.

11.0 References

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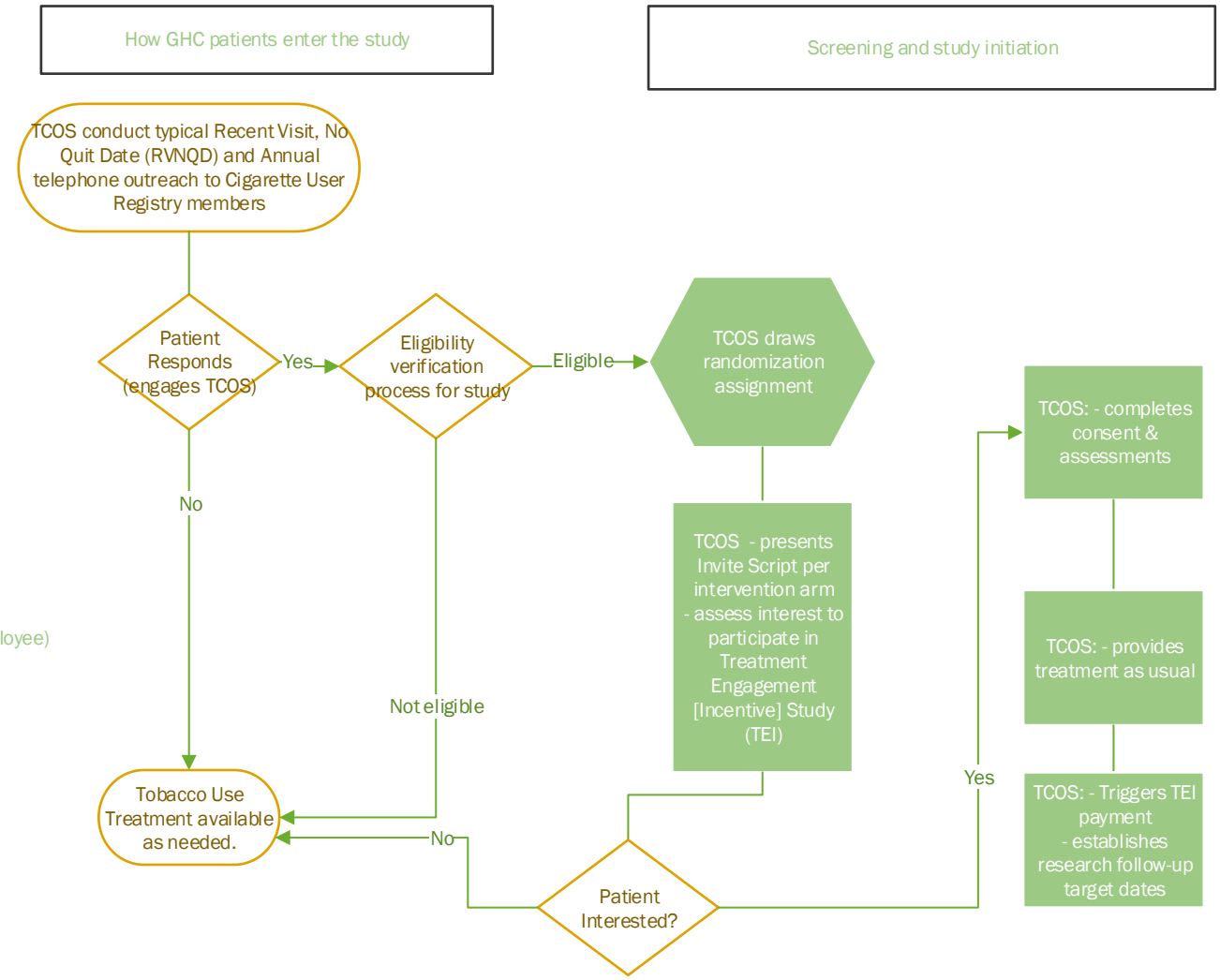
Attachment A (revised): Enrollment Flowchart

Population-based Incentive Model to Increase Smoking Cessation Treatment Engagement in Primary Care Study

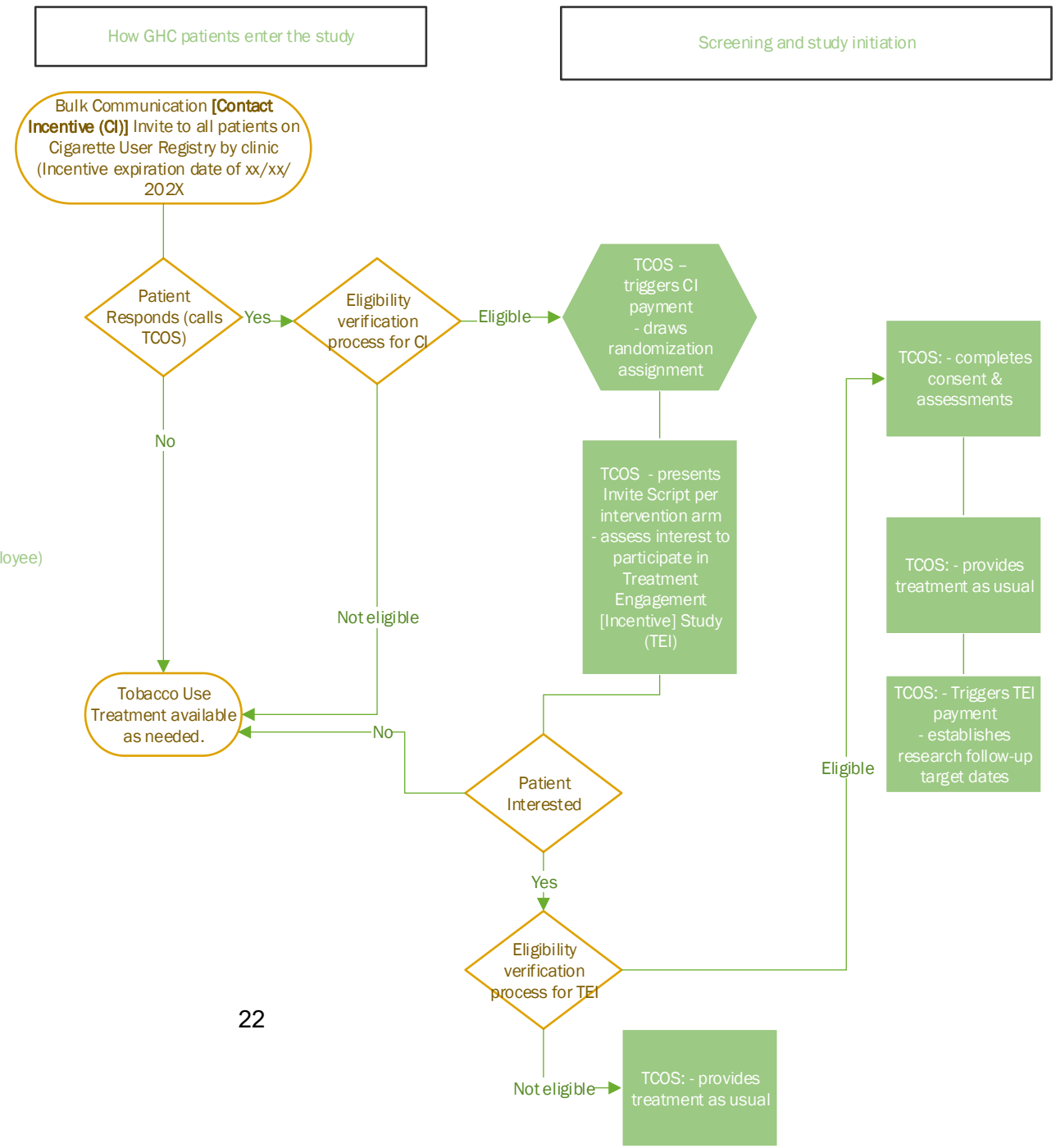
TCOS= Tobacco Cessation Outreach Specialist (GHC Employee)



Attachment A: Enrollment Flowchart

Population-based Incentive Model to Increase Smoking Cessation Treatment Engagement in Primary Care Study

TCOS= Tobacco Cessation Outreach Specialist (GHC Employee)



Attachment B. Invite scripts for Treatment Engagement Incentive Study

Discuss the purpose of of the call

Hi, I am specialist *X X* from your healthcare provider, GHC- SCW, and I've called as part of an important benefit to our patients to help them quit smoking.

Let me please confirm whom I'm speaking with. [CONFIRMS CALLER IS MEMBER OF GHC-SCW.] *We want to make sure all our patients who smoke know about the many ways we can help them with their smoking. Quitting smoking is the best thing you can do for your health, but quitting can be hard. We are here to help even if you are not ready to quit yet."*

First, can you confirm your date of birth? Check against EHR to make sure you have the correct patient on the phone.

"I see your last your last visit with us was in *Y Y*."

- Ask the patient "Are you still smoking?"

If patient initially responds they are no longer smoking, ask "So, just to confirm, you have not had even one puff over the last seven days?"

If 0, click "No" (Informational Alert should trigger with reminder to adjust Smoking Status in Vital Signs/Social History. Congratulate the patient on quitting and thank them for taking the call. If you need support contact us at xxx-xxx-xxxx.

If >0, click "Yes" advise them to quit and offer treatment: "The most important thing you can do to improve your health is to quit smoking and I can help you. I can help provide medications, and treatment support over the phone and via text messages.

Also, check against EHR that patient:

a) Is on the Cigarette User Registry for a participating clinic

b) Does not have an existing target quit date ±30 days from date of call to TCOS

c) Current billable insurance documented as other than Medicare or non-BadgerCare Medicaid

d) Preferred language is either English or Spanish

If either a, b, c, or d, is untrue→ offer tobacco use treatment or resources as per usual standard care.

IF a, b, c, & d, true→ Continue

RANDOMIZE

Randomized to $0 incentive

"As a GHC-SCW member, you may be eligible for a special study that may include receiving money for participating in treatment for those willing to make an attempt to quit smoking in the next 30 days. If you are interested, let's discuss getting you started now. Is this something you are interested in?"

Randomized to either $100, or $50 incentive

"As a GHC-SCW member, you may be eligible for $[XX] to make an attempt to quit smoking in the next 30 days. You would receive ½ of it for completing your first telephone counseling session and the rest for completing the Week 4 counseling session. If you are interested, let's discuss getting you started now. Is this something you are interested in?"

Are you interested in trying to quit smoking in the next 30 days?

N/A (I DON'T SMOKE) YES NO

NO → *Thanks, we understand that it's not always the right time to quit. OK. Would you like my direct line or the number of the Wisconsin Tobacco Quit Line?* YES NO

YES → *I can be reached 8-4 at xxx-xxxx, the quit line toll free number is: [1-800-784-8669]. Their staff are available 7 days a week, 24 hours a day.*

NO → *Thank you for your time.*

YES → *We'd like to ask you to be in a research study to help us figure out the best ways of offering this support. We at GHC-SCW and our research partners at the University of Wisconsin, or UW-Madison are trying to find ways to help smokers quit right now. If you're interested in the study, we can see if you qualify for it. If you don't qualify, or you aren't interested in the study, we still have support to offer you to quit. I can help you now or you can talk to your doctor or call the Wisconsin Tobacco Quit Line for phone coaching and 2 weeks of free nicotine replacement medication. Would you like to hear more about the study now? This will take 2 minutes.*

YES NO

GO TO TREATMENT ENGAGEMENT INCENTIVE STUDY CONSENT PROCESS.

NO→*Thanks, we understand that that this may not be the right fit. Would you like my direct line or the number of the Wisconsin Tobacco Quit Line?* YES NO

YES → *I can be reached 8-4 at xxx-xxxx, the quit line toll free number is: [1-800-784-8669]. Their staff are available 7 days a week, 24 hours a day. [confirm mailing address for Contact Incentive]*

NO → *Thank you for your time*. *[confirm mailing address for Contact Incentive]*

YES → *Great, the goal of this study is to see which ways of offering support best help people get into stop-smoking treatment. This is a 6-8 month study in which we will help you quit smoking. You may get 3 phone calls from me to talk about your quit-smoking options and plans. To begin you need to pick a target quit date within the next 30 days. Our research partners at the University of Wisconsin (UW) will call you 2 other times over 6 months to see how your quit effort went, and ask about any tobacco use and your health. You would be paid $20 for completing the 6-month phone survey. You may be asked to visit UW's tobacco treatment clinic after 6-months to check your breath, urine, and/or saliva for traces of smoking. You would be paid $50 for this visit. Your part in the study will end 6 to 8 months after you enroll, but we may collect data from GHC-SCW electronic health records from one year ago and up to 1 year from now so we can see how study treatments affect people's health and use of health care. We keep information about you confidential and use it just for research.*

Would you like to continue? YES NO

NO → *Thank you for your time*.

YES → Continue

Excellent. Now I would like to tell you more about the study, answer any questions you have, and ask if you consent to be in the study. If you do consent, the next step will be to collect more information before we end this call.

I've already told you about the study purpose and procedures. Now I want to review some reasons you may want to be in the study:

- *The study will give you opportunities to get effective treatments to stop smoking. Everyone in the study will be offered our full range of smoking cessation treatment options.*
- *You will help researchers learn how to offer stop smoking treatments in a way that helps more people quit smoking and improve their health.*

Here are some reasons you might NOT want to take part in this study:

- *The study collects information about you and your health. You might be uncomfortable providing some of this information, and you have the right to refuse to answer any question.*
- *We will protect your information from unauthorized use and disclosure, but there is still a risk that your information could become known to someone not involved in this study.*

If you get sick or hurt during this study, please get the help you need right away. Costs for any medical care will be billed to you or your insurance, just like any other medical costs. No other compensation (such as lost wages or damages) is usually available.

Any questions so far? YES _____ NO Answer questions

I mentioned we will collect information about you. This information will come from you, and from your GHC-SCW health record for up to 3 years. We'll use this information to see how our ways of offering support to smokers affect their use of stop-smoking treatment, ability to quit smoking, and overall health. Collecting information from GHC-SCW will not affect your relationship with GHC-SCW or the services you receive in any way.

GHC-SCW and the UW-Madison have strict rules to protect your personal and protected health information. We limit who has access to your name, address, phone number, and other information that can identify you. We also store this information securely. We also have a Certificate of Confidentiality from the National Institutes of Health that prohibits us from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent. The UW-Madison may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

We cannot promise complete confidentiality, however. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study, and to the National Cancer Institute, which is funding the study.

For this study, the main people who will use your information are researchers at the UW-Madison Center for Tobacco Research & Intervention.

Any questions so far? NO YES _____ Answer questions

Taking part in research is voluntary. This means that you decide if you want to be in the study and you can leave the study at any time. Your choice will not affect your relationships with GHC-SCW, UW-Madison, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. By agreeing to be in this study, you are not giving up any legal rights. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

I'm about to ask if you give your consent to be in the study and to let us collect and use your health information for study purposes. If you decide to take part in the study, I'll give you contact information for the UW-Madison research team in case you have questions. We'll also send you a written summary of all the information we discussed about this study. It will include contact information for the study team and instructions for what to do if you decide you want to leave the study, have any questions about your rights as a research participant, or have any complaints you cannot resolve with the research team.

Do you have any questions about the study? NO YES _____ Answer questions

DO YOU CONSENT TO PARTICIPATE IN THE STUDY AND ALLOW FOR THE USE OF YOUR HEALTH INFORMATION? YES NO

NO → Even without participating in the study, although you are not eligible for the financial incentive, I can help you now with medications and treatment support over the phone and via text messages or you can talk to your doctor or call the Wisconsin Tobacco Quit Line for phone coaching and 2 weeks of free nicotine replacement medication.

YES → Continue

Great! I'm so glad you've decided to join the study! We'll send you a summary of what we just talked about and additional information about the study in the mail. It will also give you the phone number of our research partners at UW-Madison.

If participant wants to get contact numbers now, provide these over the phone:

Project Principal Investigator: 608-262-8673 (questions about study)

UW Health Patient Relations: 608-263-8009 (complaints about study or team)

We are requesting your email address so we can keep in touch with you. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact [Michael C. Fiore, M.D., Principal Investigator, 608-262-8673]. You do not have to provide your email address to participate in this study.

Next I'm going to ask you to answer some questions. This should take 5-10 minutes. Is now a good time to do this? YES NO

NO → *When would be a better time to call?* Schedule a time to call back

UNSURE OF BETTER TIME → *OK. I'll call you back later to see if I can catch you at a better time. Please feel free to call me back at ###-###-#### when you have time to talk*.

YES →

Conduct baseline assessment

SCRIPT FOR LEAVING A MESSAGE ON AN ANSWERING MACHINE

Hello, my name is _____ *and I am calling from* GHC-SCW *for* **{RESPONDENT'S NAME}.** *Please call me back at* **{TCOS phone number}** *when you can.*

SCRIPT FOR LEAVING A MESSAGE FOR A PARTICIPANT WITH ANOTHER PERSON

Hello, my name is _____ *and I am calling from* GHC-SCW *for* **{RESPONDENT'S NAME}.** *Please have* **{RESPONDENT'S NAME}** *call me back at* **{TCOS phone number}** *when s/he can*.