A. Cover Page

1. Program Title: Screen, Refer and Track: A Personalized Medicine and Systems-Based Approach to Improve the Outcomes of Patients with Rheumatoid Arthritis at Risk for Cardiovascular Disease at an Academic Medical Center.

Grant ID: 14015991

Principal Co-Investigators:

Darlene Kim, MD, FACC, Assistant Professor, Department of Medicine, Division of Cardiology Barbara Goldstein, MD, MMSc, Assistant Professor, Department of Medicine, Division of Rheumatology

Interdepartmental Collaborators:

The Department of Medicine The Institutional Review Board

The Office of Professional Education The Division of Cardiology

The Division of Rheumatology The Department of Patient Quality & Safety

The Department of Clinical Nutrition Services Division of Biostatistics & Bioinformatics

QuitLine® Smoking Cessation Program FitLogix® Weight Management System

2. Abstract: The goal of this initiative is to implement a novel rheumatology-focused cardiology consultation service and intervention program for rheumatoid arthritis (RA) patients with increased risk for cardiovascular (CV) disease. Our aims include: 1) increasing patient awareness of CV risks; 2) improving the practice for screening and documenting CV risk factors; 3) increasing referrals to systems-based resources that target modifiable risk factors; 4) promoting collaboration between rheumatology and cardiology departments; and 5) demonstrating improved patient outcomes related to modifiable risk factors.

To accomplish our goals of the program, we will implement systems-based changes and provide multidisciplinary education and resources to health care providers and patients with RA at risk for CV disease. Data from the electronic medical record (EMR), FitLogix® and Quitline® weight management and smoking cessation reporting systems, and patient surveys will be collected and tracked in a project-specific data registry. This effort will provide preventive care that is patient-centered and cost-effective for the health care system, and demonstrate a systems-based process that can be replicated by other institutions nationwide.

C1. Overall Goals and Objectives:

The goal of this initiative is to implement a novel rheumatology-focused cardiology consultation service and intervention program for rheumatoid arthritis (RA) patients with increased risk for cardiovascular disease (CVD). Our aims include: 1) increasing patient awareness of CV risks; 2) improving the practice for screening and documenting CV risk factors; 3) increasing referrals to systems-based resources that target modifiable risk factors; 4) promoting collaboration between rheumatology and cardiology divisions; and 5) demonstrating improved patient outcomes related to modifiable risk factors.

A critical component of the project will be to utilize a dedicated patient case manager (PCM) to optimize the care delivered. The PCM will be trained to navigate the patient from the rheumatology visit to the cardiology consult, and then through participation in the wellness programs. In addition, the PCM will work closely with the Biostatistics and Bioinformatics department to track provider performance and patient outcomes data.

This initiative will provide education and resources to RA patients at an academic medical center who are at increased risk for cardiovascular disease, as well as multidisciplinary education and systems-based changes in processes to clinical members of the Cardiology and Rheumatology Divisions. The evaluation plan will track provider screening and documentation efforts, referrals to systems-based wellness programs to improve patient health status, improvements in patient health outcomes related to modifiable risk factors, comparative data between patient groups who participate in interventions and groups who choose to not participate, and improvements in patient awareness of modifiable risk factors. This effort will provide preventive care that is patient-centered and cost-effective for the health care system, and demonstrate a systems-based process that can be replicated by other institutions nationwide.

<u>Key Objectives:</u> To achieve the overall goal, we propose the following key objectives:

- Implement a rheumatology-focused cardiology consult to:
 - Facilitate rheumatologists' identification and screening of patients with rheumatoid arthritis (RA) and increased risk for CVD for additional risk factor assessment and modifications using a system-based method
 - Increase referrals to systems-based wellness resources to improve modifiable risk factors
 - Bolster collaborative multidisciplinary patient care
 - Increase awareness of the increased CV risk associated with RA
- Train and utilize a dedicated PCM to:
 - Identify the current or potential NJH RA patients at increased risk for CVD and engage the rheumatologist in considering the patient for the referral program
 - Periodically meet with and educate RA patients at risk for CVD, and motivate patients to participate in the recommended systems-based interventions
 - Navigate the patient through the consultative visits and participation in systemsbased wellness resources for improved patient health
 - Track program data and outcomes
 - o Follow-up with patients to make adjustments to care plans accordingly

- Report outcomes to health care team
- Perform qualitative patient focus groups to inform the patient education aspects of the initiative, and again at the conclusion of the activity to measure a change in patient awareness of risk factors
- Distribute and collect patient surveys to quantitatively measure awareness of CVD risk factors pre and post-program interventions
- Provide practical strategies to increase:
 - Patient awareness of modifiable risk factors
 - Patient awareness of their specific target goals related to modifiable risk factors (i.e., goal BP, goal weight/BMI, etc.)
 - Patient participation and adherence to systems-based health improvement tools for the management of modifiable risk factors, including weight management and smoking cessation wellness programs
- Track outcomes for patients in a program-specific registry who have been identified, referred to, and who participate in internal resources for weight management and smoking cessation, and compare participant outcomes to matched patients who elect not to participate in the interventions and report on the findings.

C2. Technical Approach:

C2a. Current Assessment of Need in Target Area: At NJH, several gaps exist in best practice care for patients with RA who are at risk for CVD. These gaps were identified through a blended approach of baseline EMR audits, interviews with members of the interdisciplinary health care team, and a peer-reviewed literature review:

- GAP: Although screening tools, such as the Framingham risk score, exist for assessing CV in RA patients, there is currently no standard or systems-based approach for screening, documenting or tracking CV risk factors at NJH.¹ A baseline EMR audit indicated that out of 784 current RA patients, 597 (76%) have additional CV risk factors, including 120 of the 784 (15%) current RA patients who smoke, and 597 out of the 784 (76%) current RA patients who are obese or at risk for obesity (have a Body Mass Index [BMI] of 25 or greater). In addition, 91 out of the 784 (12%) of the current RA patients are both smokers and are either obese or at risk for obesity (Table1).
 - <u>NEED:</u> Since NJH has a large number of RA patients with concomitant CV risk factors, there is a strong need for a patient-centered quality improvement (QI) initiative that includes **improvements in screening, documenting and referring patients** to resources to target modifiable risk factors.
- GAP: Literature indicates that efforts to modify CV risk factors are more successful when the interventions are tailored to the patient's specific needs.² In addition, studies indicate that resources are utilized more effectively when a dedicated individual, such as a PCM, is responsible for linking patients to the resources.¹⁶ NJH has built-in state of the art programs for smoking cessation and dietary, nutrition and exercise counseling; however, these programs are not currently used as risk factor modification interventions in RA patients with modifiable CV risk factors. Smoking, physical inactivity and overweight/obesity are significant issues within our RA population that can be readily targeted and modified. In

fact, EMR audits indicated that 120 of the 784 (15%) current RA patients are smokers, and 597 out of the 784 (76%) current RA patients have a BMI of 25 or greater. In addition, 91 out of the 784 (12%) of the current RA patients are both smokers and have a BMI of greater than 25 (Table 1).

<u>NEED:</u> RA patients who smoke and who are either overweight or obese are at significant risk for CVD. National Jewish Health already has built-in programs that are proven to increase smoking cessation rates and lower weight and BMI; however, since they are not currently being used with this patient population, there is a strong need for a patient-centric QI initiative **to link these patients with these resources** utilizing a dedicated individual, such as a PCM, to follow patients through the process and track patient health outcomes.

- ** It should be noted that we have chosen to focus our efforts on RA patients who smoke or who are either overweight or obese. The reason for this is twofold; 1) these patients represent a significant population within our patients with RA; and 2) we have built-in behavioral modification wellness programs that can be used to help address these populations.
- GAP: Communication barriers exist between the multiple disciplines caring for RA patients with CV risk. 3-5 At NJH, even though we have a Cardiology and Rheumatology clinic under the same roof, our set-up is not unlike other outpatient clinic settings. When patients come into the rheumatology clinic, referrals to other specialists are common, and interviews conducted with both divisions indicated that the communication and documentation sharing between departments is suboptimal. Proposed program co-investigator and rheumatologist Dr. Goldstein stated, "A program like the one proposed would help us build on our current referral process, and improve collaboration with our patients' many other health care providers."

<u>NEED:</u> Patients with RA are often seen by other health care providers for a multitude of issues. It is imperative that health care providers are referring when necessary, communicating appropriately, and are sharing timely patient-specific information. **Multidisciplinary education and systems-based process modifications** are needed to improve communication and data-sharing.

• GAP: RA patients are at an increased risk for CVD; however, patients lack awareness of the risks associated with their disease, or how to modify their behavior to help prevent the risk of CVD. ⁷ Interestingly, baseline data showed that in 2013, although almost all patients were asked their smoking status (98%), only 20% of patients who smoke were counseled to quit. Similarly, 100% of patients had a BMI recorded; however, out of the patients with a BMI of 25 or greater, only 20% were referred to a nutrition consult.

<u>NEED</u>: Although modifiable risk factors such as smoking status and BMI are recorded in the EMR, physicians at NJH are lacking in providing patients with tools and resources to help modify their behavior and improve modifiable risk factors. **Patient education and referrals to systems-based wellness resources is needed** to improve patients' awareness of the risks associated with their disease, as well as provide steps that they can take to decrease their risk. Pre and post-program **surveys and qualitative patient focus groups are needed** in

- order to drive the education developed for patients, and assess whether or not patients are more aware of the risks associated with their disease as a result of the program.
- GAP: Providers lack time to make changes in their practice. Literature indicates that providers are more likely to change practice behaviors when; 1) quantitative data proves that their behavior change will result in improved patient health⁸; and 2) the practice is redesigned in a coordinated care effort, utilizing a combination of brief counseling coupled with a referral to a valued counseling resource.⁹

<u>NEED</u>: There is a **need to provide patient-centric outcomes** that can be disseminated to a broad audience of health care professionals to demonstrate that counseling RA patients on smoking cessation and weight management, and providing resources for modification, can improve outcomes. Second, there is a need to incorporate a **coordinated care effort as a systems-based change** to make "doing the right thing" for the provider the default option. The time-burden can be addressed by coupling brief counseling with a referral to a non-physician resource or intervention.

C2a1. Baseline Data Summary

Table 1. Baseline Data and Outcomes Goals

	NJH Baseline Assessment	Program Outcomes Goal
Number of Patients at NJH with RA	N=784	
% of Patients with RA and additional CV risk factors	76%	
% of patients with RA with a CV risk assessment	0%	95%
% of Patients who had smoking status documented	98%	100%
% of patients with RA who smoke	15%	5%
% of patients with RA with a BMI of 25 or greater	76%	66%
% of patients with RA who smoke and have a BMI of 25 or greater	12%	10%
Number of patients with RA with a BMI of 25 or greater	N= 597	
% of patients with RA with a BMI of 25 or greater who were referred to Nutrition Consult	11%	95%
% of patients with RA with a BMI of 25 or greater who were referred to FitLogix®	0%	95%
Number of patients with RA who smoke	N= 121	
% of patients with RA who smoke who smoke who were counseled to quit	20%	95%
% of patients with RA who smoke who were referred to the QuitLine®	0%	95%

C2a2.Primary Audience: The primary target population for this initiative is patients with RA who are at additional risk for CVD. In 2013, 784 patients with RA were seen at NJH; 597 of those patients were overweight or obese, and 121 of those patients smoked. The sample size is reasonable based on time and cost-constraints of this study, and adequate to show the practical value of the interventions discussed in this proposal. We anticipate that at least 200 patients will enroll and participate in FitLogix®, with at least 100 patients completing the 12-month program, and another 100 patients will complete a nutrition consult. We expect at least 50 patients to participate in the Quitline® program, and another 100 patients will benefit from smoking cessation counseling from their physician. In addition, the population of RA patients with these modifiable risk factors is very generalizable. The insurer breakout is as follows: approximately 1/3 is insured by Medicaid or Medicare, 1/3 by private insurance, and 1/3 classified as "other." The majority of patients lack access to care, are underserved, and underrepresented. These patients will directly benefit from the project by improved outcomes, and the health care system will indirectly benefit from this project by projected decreased health care utilization costs.

The secondary target population includes the multidisciplinary health care professionals within the cardiology and rheumatology divisions at NJH. In addition, project outcomes will be compiled and disseminated so that health care providers nationally can learn from this study and create systems internally to screen, educate and refer patients in their own practices.

Although we recognize that it may not be financially feasible for all practices to employ a PCM to navigate and track patients, it should be noted that it isn't necessary to have internal, built-in resources like Quitline® and Fitlogix® in order to replicate this type of program. Health care providers can refer smokers to free quitline services in all 50 U.S. states, Puerto Rico, Guam and the District of Columbia. In addition, there are a multitude of free resources for weight management that health care providers can utilize. In addition to referring patients to in-house nutritionists and dieticians for education and counseling (if available), providers can share free resources that promote physical activity and healthy eating, such as the "Lose It!" weight loss tracking system that is available on the web or as a downloadable smartphone application. 10

<u>C2b. Intervention Design and Methods:</u> The Plan-Do-Study-Act (PDSA) cycle, the specific framework/methodology chosen to guide this initiative, is a component of the Institute for Healthcare Improvement Model for Improvement.¹¹ The PDSA framework is a simple yet powerful tool for accelerating QI. Once a team has set an aim, established its membership, and developed measures to determine whether a change leads to an improvement, the next step is to test a change in the real work setting. The PDSA cycle is shorthand for testing a change — by planning it, trying it, observing the results, and acting on what is learned (Diagram 1).

Diagram 1: The PDSA Cycle



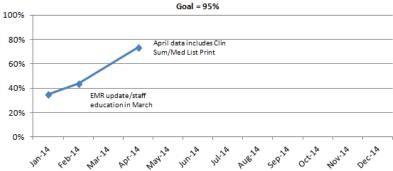
Experience with PDSA: NJH has extensive experience in planning, implementing and studying programs using the PDSA framework for design. In July of 2013, the Office of Professional Education at NJH collaborated with multiple departments to implement an institution-wide quality and performance improvement initiative titled, "Best Practices for Medication Reconciliation at a Respiratory Academic Medical Center," a program aimed to improve the process of medication reconciliation, a 2012 requirement by the Joint Commission to ensure patient safety and accuracy of medications. ¹² The two year program is multifaceted, and targets provider performance measures, patient education and adherence strategies, and multiple components of systems-based change. Preliminary outcomes have indicated significant improvements in the percentage of patients whose medications are reconciled at the time of visit, and the percentage of patients who receive a printed and reconciled list before leaving the practice (Tables 2 and 3).

Table 2: Meds Reconciled % Adult Clinic Patients with Meds Reconciled



Table 3: Printed Med List Received





In 2012, NJH, in collaboration with three hospitals and a primary care practice in rural, southeast Colorado, designed and conducted a quality and performance improvement initiative using the PDSA framework titled, "Meeting the Needs of Rural Colorado: Implementing Sustainable Evidence-Based Asthma Care." The program was focused on improving the delivery of evidence-based asthma care through multiple interventions, including the use of spirometry, patient visit checklists, in-clinic trainings, and the development of patient education resources to promote disease self-management. At the conclusion of the two-year initiative, all indicators of quality asthma care demonstrated statistically-significant and clinically meaningful improvements (table 4).

Table 4: Asthma Program Results

Indicator	Baseline(n=430)	Post (n=337)	Goal*	P value
Spirometry (peak flow included only for baseline)	3% (13)	14% (47)	50%	0.001
Asthma control PARTIAL	59% (255)	67% (225)	N/A	0.01
Asthma control COMPLETE	1% (6)	20% (67)	50%	0.001
PRN Reliever inhaler	55% (238)	94% (317)	100%	0.001
Controller medicine	39% (168)	71% (238)	60%	0.001
Inhaler technique	1% (5)	18% (60)	100%	0.001
Asthma action plan	2% (8)	29% (99)	15%	0.001
Follow-up visit	20% (87)	37% (123)	50%	0.001

The PDSA cycle uses the following stepwise approach, which we have modified to also meet the requirements of the American Medical Association's (AMA) format for performance improvement CME (PI CME). PI CME is a three-step process that begins with a self-assessment of current practice using identified performance measures (Stage A), the implementation of a set of interventions designed for sustained improvement of patient care (Stage B), and the completion of a follow-up self-assessment with the same measures to assess improvements (Stage C). NJH is accredited with commendation by the Accreditation Council for Continuing Medical Education (ACCME), and will award physicians who complete all stages of the PI CME initiative with 20 AMA PRA Category 1 Credit(s). ™

The Approach:

Stage A: Plan (Months 1-4)

Using the PDSA's stepwise approach as a method for success, a multidepartmental "practice redesign" team reviewed the current process for identifying, screening and targeting modifiable risk factors, as described earlier in this proposal. Based on the identified gaps in the current process, the following will occur in the first 4 months of the initiative:

1. Baseline EMR reports will be distributed to individual providers so that they can assess their own performance on the specific performance-related indicators, which include documentation of screening for CV risk factors, as well as if an action was taken by the provider to help modify risk factors (Table 5).

Table 5: Sample Provider Feedback Report

Category	Criteria	Threshold	Baseline	2 mor	nths	2 mo	nths	2 mc	onths	OVE	RALL
				#	%	#	%	#	%	#	%
Provider Performance	% of RA patients referred to cardiology for CV risk assessment	95%									
	% of patients with BMI of 25 or greater referred to nutrition consult	95%									
	% of patients with BMI of 25 or greater referred to FitLogix*	95%									
	% of RA patients with smoking status documented	100%									
	% of RA patients with positive smoking status referred to Quitline*	95%									
	% of RA patients with positive smoking status who received a cessation intervention	95%									

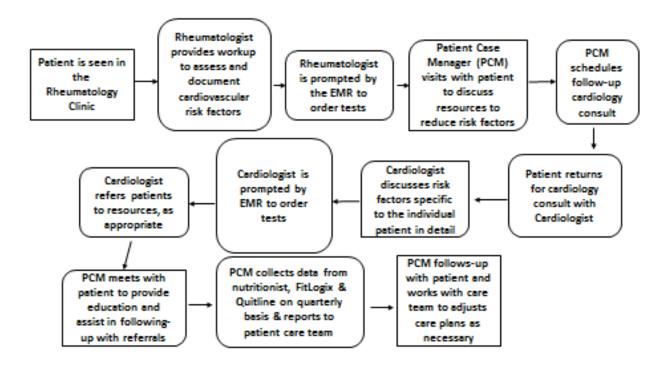
^{*} These criteria will have a baseline of 0, as they are not included in the current process at NJH, and will be implemented as components of this study.

- 2. Providers will be asked to complete a self-reflection survey in response to their feedback reports on key quality performance measures. Self-reflection is a step in the PI CME format, and will help the individual provider identify where his or her gaps are most prevalent, and identify areas where practice can be adjusted to make significant improvements over time.
- **3.** Continued engagement from the Cardiology and Rheumatology Department teams in the process redesign plan (table 6), including:
 - a. The identification of a new screening and documentation strategy utilizing the Framingham risk score assessment tool and atherosclerotic cardiovascular disease (ASCVD) risk estimator, as well as the development of a CV risk template that will be tracked in the EMR, which will assist with project data capturing and to prompt providers to order necessary tests.¹⁸
 - b. The incorporation of a PCM to educate, navigate and track patients through the new processes and report back to the health care team.
 - c. The development and implementation of a cardiology consult where the European League Against Rheumatism/American College of Rheumatology (EULAR/ACR) CV

risks and The American College of Cardiology Foundation/American Heart Association Task Force (ACCF/AHA) CV risks will be addressed, and patients will be assessed for smoking and obesity/risk for obesity, educated by the physician and the PCM, and referred to a nutritionist, Quitline® or FitLogix® as appropriate. 4,15

- **4.** Pre-program patient focus groups to; 1) identify major barriers in adherence; 2) create strategies for patient education; and 3) assess awareness of risk factors.
- **5.** Pre-program patient surveys to measure awareness of risk factors.

Table 6. Planned Process Flow



Stage B: Do (Month 5-24)

- **1.** Every 4 months throughout stage B, education and training will be disseminated to the cardiology and rheumatology divisions, which include 13 medical doctors, 6 registered nurses, 4 medical assistants, 4 imaging technicians, and 3 exercise physiologists.
 - a. Content will address the gaps identified in section C2a, including screening and documentation process flow changes and new scoring tools, incorporation of a PCM, provider-to-provider communication strategies, provider-to-patient communication strategies, patient adherence, EULAR CV Risk Management Recommendations and ACCF/AHA CV Risk Guidelines, as well as the use of referrals to systems-based smoking and weight management wellness resources at NJH.
 - The format of the education will include in-clinic, multidisciplinary team trainings that will include interactive lecture, role-play demonstrations and EMR documentation training. In addition, providers will be assessing their data on

multiple occasions throughout the project in order to self-assess/benchmark, identify areas of improvement, and create strategies to meet goals.

- 2. Education, tools and resources will be provided to RA patients at risk for CVD.
 - a. Content will be created based on patient feedback captured in the patient focus groups convened in stage A. The content will address the gaps identified in section C2a, including an overview of risk factors associated with their disease, tools and resources for modification of modifiable risk factors, adherence to medications, individual goal plans, and effective patient-to-provider communication strategies.
 - b. Education will be delivered to patients via interactive discussions with their providers and the PCM at the time of visit (rheumatology visit and the cardiology consult), printed supplemental materials, as well as referrals to the following evidence-based behavioral health wellness interventions:
 - (1) NJH QuitLine® Program: personalized tobacco cessation program to help motivate and guide individuals who want to give up tobacco for life. QuitLine® offers up to five proactive coaching sessions customized to each participant, with a 24/7 accessible website that provides access to tailored motivational messages, step-by-step guides to cutting down and quitting tobacco, as well as an online support forum with other quitters and quitting specialists. Aggregate Qutline® outcomes show an average quit rate of 42.7%, which is a 14.3% increase in comparison of the quit rates for smokers who do not use an evidence-based quitline intervention.
 - (2) NJH Fitlogix®: medical-oriented behavioral change program with state-of-the-art weight and activity monitoring systems (including a pedometer, scale and dashboard given to all enrolled patients), one-on-one telephonic coaching, 52 weeks of lesson plans, and online support. Aggregate FitLogix® outcomes show an average 6% reduction in weight from baseline after 12 months (5% is considered clinically significant by the FDA), translating into an average reduction of \$2,487 in medical claims data per person in one year.

Stage C: Study & Act (Months 24-28)

- **1.** Post-program objective data reports will be distributed to providers in the same format as described in Stage A.
- 2. Providers will be asked to complete a self-assessment survey in response to their change in performance as a result of the initiative, as well as comment on their overall engagement and level of satisfaction with the initiative.
- **3.** Post-program results will be compared with baseline, and the outcomes of patients who participated in the interventions will be compared with those who elected not to participate (control group), and results will be shared with providers and teams.
- **4.** Post-initiative focus groups with patients will be conducted to assess improved awareness of risk factors and overall experience in participating in systems-based resources for behavior modification.
- **5.** Post-program patient surveys will be collected to measure a change in patient awareness of risk factors.

6. The process will be modified as necessary, based on the outcomes of the initiative and feedback from the participants (including patients and providers).

C2c. Evaluation Design

C2c1. Was the gap addressed? This initiative was designed to have multiple data points to measure outcomes related to provider performance, patient health outcomes as a result of the application of interventions, and outcomes related to improved patient awareness.

Quantitative Outcomes:

(In addition to reporting on percentages, as listed below, the Biostatistics and Bioinformatics team will use statistical software to determine changes in all outcomes)

Provider performance outcomes will include **provider-specific** and **aggregate** pre and post-program data on the following indicators:

- % of RA patients with documented CV risk assessment
- % of RA patients who had smoking status documented
- % of RA patients with BMI of 25 or greater referred to nutrition consult
- % of RA patients with BMI of 25 or greater referred to FitLogix®
- % of RA patients with smoking status documented
- % of RA patients with positive smoking status referred to Quitline®
- % of RA patients with positive smoking status who received a cessation intervention

In addition, we will include the following **aggregate** pre and post-program data on the following (as described in Table 1):

- % of Patients with RA and Additional CV Risk Factors
- % of patients with RA who smoke
- % of patients with RA with a BMI of 25 or greater

Patient awareness outcomes will include pre and post-data on the following:

- % of patients who are aware that RA increases risk for CVD
- % of patients who understand the term "modifiable risk factor"
- % of patients who know whether or not they have a modifiable risk factor
- % of patients who are familiar with the term Body Mass Index (BMI)
- % of patients who know their BMI
- % of patients who can correctly identify at least three health problems that are related to obesity
- % of patient who can correctly identify at least three health problems that are related to smoking

We will also provide patient health outcomes on the group of patients who participate the resources that are implemented as part of this initiative, including the nutrition consult, the FitLogix® weight management system, and the Quitline® smoking cessation program. These

outcomes will be compared to a matching group of patients who elect not to participate in the interventions (control group). The data will be captured in similar tables as illustrated below (Tables 7 and 8). Baseline for these groups will be collected during the cardiology consult visit, and will be patient-specific, so that we can compare outcomes at pre and post-intervention.

Table 7: Comparative outcomes related to weight management

	RA patients who participate in FitLogix®			RA patients who complete nutrition consult			RA patients who do not utilize weight management resources		
	Pre	Post	Pre- Post Change	Pre	Post	Pre- Post Change	Pre	Post	Pre- Post Change
Framingham Index Score									
ASCVD 10 year risk									
Lifetime risk									
Blood Pressure									
Fasting Lipids									
Glucose Levels/Hgb A1C									
Antihypertensive Added/Adjusted									
Lipid Lowering Agents Added/Adjusted									
C-Reactive Protein									
Weight									
BMI									
Average Steps per Day (Physical Activity)									

Table 8: Comparative outcomes related to smoking

	RA patients who smoke who participate in Quitline®			RA patients who smoke who do not participate in Quitline®			
	Pre	Post	Pre-Post	Pre	Post	Pre-Post	
			Change			Change	
Framingham Index Score							
ASCVD							
10 year risk							
Lifetime Risk							
Blood Pressure							
Fasting Lipids							
Glucose Levels/Hgb A1C							
Antihypertensive							
Added/Adjusted							
Lipid Lowering Agents							
Added/Adjusted							
C-Reactive Protein							
Smoking Status							

Qualitative Outcomes:

Information from the pre and post-program patient focus groups will be analyzed and we will report on a change in patient awareness of risk factors associated with their disease. We anticipate that based on the many interventions that will be implemented in this initiative, patients will be significantly more aware of risk factors associated with their disease at the completion of this program, and steps that they can take to reduce their risk of CVD. In addition, other aggregate information captured in the provider self-assessment surveys, as well as informal post-program interviews with members of the multidisciplinary health care teams, will be compiled and reported. This will include program satisfaction, barriers encountered, and perceptions related to the programs' effect on multidisciplinary collaboration.

C2c2: **Data Collection:** NJH is in the unique position to have a dedicated department to collect and analyze data for quality improvement initiatives. The Department of Biostatics and Bioinformatics manages a research database and repository that will be used to collect and report data for this initiative. Trained members of the Biostatics and Bioinformatics team will be collecting data from the EMR as well as patient-specific reports from FitLogix® and Quitline®. The PCM will work closely with this team to track outcomes on patients so that they can follow-up with patients as necessary, and share information with the health care team.

Because of the nature of this patient-centric initiative, including contacting patients for participation as well as the collection of patient-specific data, we will submit an application to the NJH Institutional Review Board to assure that all regulatory procedures and requirements for conducting human subject research are met.

C2c3: Quantifying Outcomes: As described in *Table 1*, we expect provider performance outcomes to increase significantly on the provider-specific indicators. Three of these indicators are entirely new processes for providers, so they are beginning at 0, and our outcomes goal for each is 95% (documentation of CV assessment, referrals to FitLogix® and Quitline®). We expect significant improvements in the additional performance-related indicators, including an 84% increase in referrals to nutrition consult for RA patients who are obese or at risk for obesity, and a 75% increase in counseling RA patients who smoke to quit smoking. Since baseline data indicates that providers are already documenting smoking status 98% of the time, we will attempt to increase this indicator by 2%. In addition to percentage increases on these indicators, the Biostatics and Bioinformatics team will perform statistical analyses to quantify improvements in the outcomes over the total population (example: percent of smoking cessation correlated with adherence to Quitline®, etc.).

In the groups of patients who participate in weight management and smoking cessation resources: We estimate 5% improvements from baseline for the indicators listed in Tables 7 and 8 above for the patients who participate and complete the Quitline® and FitLogix® programs. We anticipate that at least 30% of patients who participate in the Quitline® will have quit smoking by the completion of the program, and that 67% of patients who complete the FitLogix® program will lose 3-6% of their baseline weight, an average of 1-2% reduction in BMI, and increase steps per day by 10%. For patients with a BMI of 25 or greater who do not participate in FitLogix®, but who do complete a nutrition consult, we anticipate improvements of 1-2% over baseline.

Patient awareness is another measureable outcome of this study. We will be conducting patient focus groups and well as distributing and analyzing surveys to measure a change in patient awareness of risk factors related to their disease, specifically related to BMI and smoking. We expect that awareness of risk factors and modifications to reduce risk will significantly improve as a result of this program.

C2c4. Audience Engagement: Audience engagement will be determined by several factors:

Providers:

- 1. Information collected in the provider self-assessment surveys
- 2. Information collected in the informal provider interviews
- 3. Improvements in provider-specific outcomes data

Patients

- 1. Information collected in pre and post-program patient focus groups and surveys
- 2. FitLogix® and Quitline® patient-specific outcomes data, including number of counseling sessions and amount of time spent in the program.

C2c5: Dissemination Plan: Our goal is that this project is sustainable internally, and also replicable by other organizations; thus, aggregate data will be shared organizationally, locally, and nationally. A summary of educational outcomes will be published on NJH's website, www.njhealth.org/education. In addition, we will submit an abstract for presentation at one or more of the following conferences: American College of Rheumatology (ACR), European League Against Rheumatism (EULAR), American College of Cardiology (ACC), American Heart Association (AHA). Lastly, we will submit a manuscript to one or more of the following peer-reviewed journals: Arthritis and Rheumatology, Arthritis Care and Research, Journal of the American College of Cardiology, and the American Journal of Cardiology. We will also submit a manuscript to the Journal of continuing Education in the Health Professions.

<u>C3: Detailed Workplan and Deliverables Schedule:</u> The workplan and deliverables are described in detail in section C2b, page 10- 13, and summarized below (Table 9).

Table 9: Workplan and Deliverables Summary

Milestone and Deliverable Description	Month Completed
Stage A: Plan	
Identify and Train PCM	12/14
 Collect baseline provider-specific data; provide feedback reports and self- assessment surveys 	12/14
Create fields in EMR for CV Risk Template and create prompts	11/14
Fine-tune processes for cardiology consult and tweak process flow chart	12/14
Conduct patient focus groups & collect patient surveys	12/14
Stage B: Do	
Implement processes defined in Stage A	
Provide quarterly in-clinic educational interventions to health care teams	4/15; 5/15; 12/15; 5/16
Develop patient education tools and resources	5/15
Stage C: Study & Act	
 Collect post-program provider specific data; provide feedback reports and self- assessment surveys 	9/16
Conduct post-program patient focus groups	10/16
Compile all outcomes results as described in C2c	11/16
Make adjustments to processes based on outcomes results	12/16
Disseminate outcomes internally and externally	1/17

References:

- 1. Wilson PW, D'Agostino RB, Levy D et al. Prediction of coronary heart disease using risk factor categories. Circulation 1998; 1837-1847.
- 2. National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatement of High Cholesterol in Adults (Adult Treatment Panel III). Circulation 2002; 106:3143-3421.
- 3. Van den Oever IAM, Van Sijl AM, Nurmohamed, MT. Management of cardiovascular risk in patients with rheumatoid arthritis: evidence and expert opinion. *Ther Adv Musculoskel Dis*. 2013; 5(4):166-181.
- 4. Peters MJL, Symmoms DPM, McCarey D et al. EULAR evidence-based recommendations for cardiovascular risk management in patients with rheumatoid arthritis and other forms of inflammatory arthritis. *Ann Rheum Dis.* 2010;69:325-331.
- 5. Redelmeier DA, Tan SH, Booth GL. Treatment of unrelated disorders in patients with chronic medical disease. *N Engl J Med*. 1998:338:1516-1520.
- 6. Barbara Goldstein, MD. Informal interview. 20 May 2014.
- 7. Crowon CS, Gabriel SE. Towards improving cardiovascular risk management in patients with rheumatoid arthritis: the need for accurate risk assessment. *Ann Rheum Dis.* 2011;70:719-721.
- 8. Kolb, A.Y., & Kolb, D.A. The Kolb Learning Style Inventory Version 3.1: 2005 Technical Specifications. Haygroup: Experience Based Learning Systems Inc.
- 9. Cohen, DJ, Ballasubramanian, BA, Isaacson, NF, Clarke, RS, et al. Coordination of health behavior counseling in primary care. *Ann Fam Med.* 2011:September, 9(5):406-415.
- 10. Lose It!. (2014). Retrieved from https://www.loseit.com.
- 11. Inst. for Healthcare Improvement. Science of Improvement: Testing Changes. Available at: www.ihi.org/knowledge/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx.
- 12. The Joint Commission. National Patient Safety Goals. 2012; http://www.jointcommission.org/standards_information/npsgs.aspx. Retrieved October 30, 2012.
- 14. Physician's Recognition Award and Credit System. Retrieved May 28, 2014 from https://www.ama-assn.org/ama/pub/education-careers/continuing-medical-education/physicians-recognition-award-credit-system.page.
- 15. Greenland, P, Alpert, JS, Beller, GA, et al. American College of Cardiology Foundation, American Heart Association. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2010;56:e50-103.

- 16. Hickam DH, Weiss JW, Guise J-M, Buckley D, Motu'apuaka M, Graham E, Wasson N, Saha S. Outpatient Case Management for Adults With Medical Illness and Complex Care Needs. Agency for Healthcare Research and Quality; January 2013.
- 17. Traditional cardiovascular risk factors, inflammation and cardiovascular risk in rheumatoid arthritis. Liao KP, Solomon DH. *Rheumatology (Oxford)*. 2013 Jan;52(1):45-52. doi: 10.1093/rheumatology/kes243. Epub 2012 Sep 16. Review. PMID:22986289.
- 18. Goff DC Jr. et al. 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Retrieved from http://circ.ahajournals.org/content/early/2013/11/01.cir0000437741.48606.98.citation.

A. Leadership and Organizational Capability:

National Jewish Health is known worldwide for treatment of patients with respiratory, cardiac, immune and related disorders, and for groundbreaking medical research. Founded in 1899 as a nonprofit hospital, National Jewish Health remains the only facility in the world dedicated exclusively to these disorders. National Jewish Health has ranked as the number one or number two hospital in pulmonology on the U.S. News & World Report Best Hospitals list ever since pulmonology was included in the rankings.

The Office of Professional Education at National Jewish Health has been accredited by the ACCME since its inception in 1984. It was awarded Accreditation with Commendation from the ACCME in 2011, specifically recognized for its ability to act as a physician's change agent.

At National Jewish Health, we are pioneering the new era of preventative and personalized medicine by integrating the latest scientific discoveries and coordinated care for lung, heart, and immune diseases. Our institution boasts a multidisciplinary and team-based approach to care that focuses on the whole patient. National Jewish Health teams, including Cardiology and Rheumatology Departments, are dedicated to participating in quality improvement initiatives that improve interdepartmental interactions, enhance the patient's experience, and improve patient health.

In response to this request for proposal, we have developed an interdepartmental "practice redesign" team that is dedicated to achieving the goals of the project. The team consists of both clinical and non-clinical members, and includes representatives from the following departments with the corresponding key roles:

Department	Role
The Office of Professional Education	Program Management & Accreditation
The Division of Cardiology	Multidisciplinary participation in QI activity;
	Principal Investigator contribution; co-
	management of the Patient Case Manager (PCM)
The Division of Rheumatology	Multidisciplinary participation in QI activity;
	Principal Investigator contribution; co-
	management of the PCM
The Department of Patient Quality & Safety	Oversight of QI activity
Institutional Review Board	Oversight to assure activity meets all standards of
	human subject research
The Department of Clinical Nutrition Services	Participation in referral process and collaborations
	with Rheumatology & Cardiology Divisions
The Division of Biostatistics & Bioinformatics	Data collection and analysis
QuitLine® Smoking Cessation Program	Counseling and resources for study patient
	population; data sharing
FitLogix® Weight Management System	Counseling and resources for study patient
	population; data sharing

Key interventions that will be utilized and tested as part of this initiative include National Jewish Health's Quitline® and FitLogix® Programs.

FitLogix: A Behavior Weight Management Program

Drawing on our expertise in the research and treatment of respiratory illnesses and our leading edge disease management programs, NJH created FitLogix®, our effective and comprehensive program weight management. Since its inception, FitLogix® has provided services to over 15,000 participants. The majority of FitLogix® customers are major health plans and corporations who recognize the return on investment that the FitLogix® weight management system provides. In addition, through a private foundation grant, we are offering FitLogix® to 2,000 overweight or obese patients in two Denver-based Federally Qualified Health Centers.

The FitLogix® program helps individuals change their diet and exercise habits through behavior modification in order to lose weight and improve overall health. FitLogix® is designed based on clinical guidelines for screening and management of obesity in adults recommended by the US Preventive Services Task Force, clinically-proven interventions for behavior modification, and proprietary techniques developed at NJH. The FitLogix® program is designed to be completed in one year.

FitLogix® offers offers self-paced activity and nutrition modules, equipment to help track fitness and weight progress, and planned coaching calls to encourage, educate and support healthy lifestyle changes. The guidelines below are recommended based on BMI level and co-existing medical conditions, but there may be some crossover among levels. Participants will work with coaches to determine the program level that best fits their individual health needs.

FitLogix® includes:

- 52 Healthy Steps lesson modules completed throughout the year
- A series of (13) planned coaching calls to encourage, educate and support healthy lifestyle changes
- An activity meter that allows tracking of activity levels
- An activity log to track exercise not captured by the activity meter
- A digital scale that allows tracking of weight
- A personal interactive online dashboard to track information gathered from the monitoring devices
- A mobile app (iPhone, Android) for displaying the online dashboard

The Quitline®: A Behavior Weight Management Program

Drawing on our expertise in the research and treatment of respiratory illnesses and our leading edge disease management programs, NJH created Quitline,® our effective and comprehensive program for tobacco prevention and cessation. Quitline follows best practices and industry standards as published by the CDC and NAQC. Our cessation programs consistently achieve one of the highest quit smoking rates in the country, and employ the following components:

- Trained coaches who use a behavioral change model for smoking cessation
- Smoking cessation therapy options
- Educational materials

Online, text and email support

B. Staff Capacity

<u>Co-Principal Investigator – Barbara Goldstein, MD, MMSc, Assistant Professor, Department of Medicine, Division of Rheumatology:</u> Dr. Goldstein will serve as the co-leader of this initiative, and will oversee all aspects of program planning, implementation and outcomes, as well as manage the PCM. Dr. Goldstein has extensive experience in studying CV risks related to RA, and has participated and led QI initiatives.

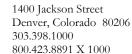
<u>Co-Principal Investigator – Darlene Kim, MD, Assistant Professor, Department of Medicine, Division of Cardiology:</u> Dr. Kim will serve as the co-leader of this initiative, and will work closely with Dr. Goldstein to oversee all aspects of program planning, implementation and outcomes, as well as manage the PCM. Dr. Kim has extensive experience in participating and leading QI initiatives.

<u>Project Manager – Sarah Meadows, MS, CCMEP:</u> Ms. Meadows is the Manager of Accreditation and Programs in the Office of Professional Education at NJH, and will oversee her team of program coordinators in the day to day management of this project, including the scheduling of planning meetings to convene all members of the program planning committee to develop, implement, and measure the quality improvement initiative. Ms. Meadows is extremely experienced in implementing, completing and reporting on quality improvement initiatives, and will utilize a built-in task management system to insure the project remains on schedule.

<u>Program Coordinator – Mandy Comeau:</u> Ms. Comeau will work directly with Ms. Meadows to ensure that all components of this program are on schedule, and will assist in coordinating all logistics of the QI initiative. Ms. Comeau will record all planning and implementation meeting minutes, and liaise between different departments working on this project. Mandy has been employed by NJH for 13 years, and will be an excellent asset to this project by keeping the many departments working on this project on track.

<u>Partner Liaison and Reporting - Meg Burke Dingae, MHSA, CCMEP:</u> Ms. Dingae is the Manager of Educational Grants and Collaborations in the Office of Professional Education at National Jewish Health, and has managed the evaluation and reporting aspects for dozens of CME activities, including multi-year, interdisciplinary PI an QI initiatives. She will be responsible for liaising with all collaborative partners for this project by coordinating planning meetings, preparing updates, compiling the outcomes and evaluation reports, and communicating results to the funder.

<u>Patient Case Manager – TBD:</u> The Patient Case Manager (PCM) is an integral component of this initiative. This individual will be co-managed by the Cardiology and Rheumatology departments, and will report directly to Drs. Kim and Goldstein. The PCM will be a master's level professional with experience in patient education, clinical trials, epidemiology and clinical care. The PCM will serve as a "navigator" and provide patient education, as well as link patients to programmatic interventions, and track patient outcomes. The PCM will work closely with members of the Biostatics and Bioinformatics department to collect all data in a program-specific registry.





Science Transforming Life®

Leading Respiratory Hospital in the US

May 30, 2014

Pfizer Independent Grants for Learning & Change Team

Re: Letter of Commitment to Develop and Implement:

"Screen, Refer and Track: A Personalized Medicine and Systems-Based Approach to Improve the Outcomes of Patients with Rheumatoid Arthritis at Risk for Cardiovascular Disease at an Academic Medical Center"

Dear Pfizer Independent Grants for Learning & Change Team:

We very much appreciate Pfizer's invitation to submit a full proposal for the recent CV risk in RA RFP, and appreciate your consideration of our attached proposal.

I am writing to express my support for the "Screen, Refer and Track: A Personalized Medicine and Systems-Based Approach to Improve the Outcomes of Patients with Rheumatoid Arthritis at Risk for Cardiovascular Disease at an Academic Medical Center" collaborative grant application to develop and implement an innovative, multidisciplinary and systems-based quality improvement initiative designed to 1) increase patient awareness of CV risks; 2) improve the practice for screening and documenting CV risk factors; 3) increase referrals to systems-based resources that target modifiable risk factors; 4) promote collaboration between rheumatology and cardiology departments; and 5) and demonstrate improved patient outcomes related to modifiable risk factors.

National Jewish Health is a 501 (c)(3) non-profit organization that provides quality integrated and innovative care for patients and their families, finds cures for the diseases we research, and educates and trains the next generation of healthcare professionals to be leaders in medicine and science. As the #1 respiratory hospital in the U.S. for 15 consecutive years, a leader in research related to infectious diseases, a center of excellence in respiratory, cardiology and immunologic diseases, as well as and ACCME-accredited provider, we are committed to high-quality patient care that improves outcomes.

National Jewish Health is excited to support this proposal by leveraging our experienced Office of Professional Education staff of seven FTEs, including three Certified Continuing Medical Education Professionals (CCMEPs), a Certified Meeting Professional (CMP), and a Certified Health Education Specialist (CHES). In addition to the Professional Education staff, an interdisciplinary "practice redesign team" that has been developed for this program includes members of the following Divisions: The Department of Medicine; The Division of Cardiology; The Division of Rheumatology; The Department of Patient Quality and Safety; The Department of Clinical Nutrition Services; The Division of Biostatistics & Bioinformatics; QuitLine® Smoking Cessation Program; FitLogix® Weight Management System; and the Institutional Review

Board. We will work diligently to ensure our goals are aligned with the goals of the grant proposal, including efforts to track and report on outcomes. In addition, we will ensure that all resources are appropriately allocated.

Sincerely,

Andrea Harshman, MHA, CCMEP, CMP Director of Professional Education

National Jewish Health