A. Cover Page

1. Identifying Information

Program Title: **Motivational Interviewing as a Patient-Centered Behavioral Intervention to Improve Medication Adherence in Rheumatoid Arthritis Patients with Inadequately Controlled Disease Activity**

Grant ID number: **9064737**

2. Abstract:

The overall goal of the proposed initiative is to investigate the effectiveness of motivational interviewing (MINT) as a behavioral intervention to improve medication adherence as part of an established patient-centered disease management program for patients with rheumatoid arthritis (RA). Using the self-determination theory of health behavior as our conceptual framework, we will evaluate the effect of motivational interviewing (MINT) as part of a patient-centered intervention to improve medication adherence. ***We propose a non-randomized single intervention study to determine whether MINT can improve medication adherence.*** This study will leverage the large RA population across the NYU campus, with our established patient-centered RA disease management program and clinical research infrastructure. We will perform MINT on 200 RA patients with inadequately controlled RA disease activity (moderate or high disease activity) who are receiving at least one oral disease modifying anti-rheumatic medication (DMARD). Our key objectives are two-fold: 1) We expect to identify patient-specific barriers to be addressed via MINT that will improve medication adherence; 2) We anticipate improvement in medication adherence associated with a MINT intervention as part of an ongoing systematic disease activity management program for RA patients. We will evaluate the effectiveness of MINT by calculating the improvement in the Medication Possession Ratio (MPR) after 6 months of MINT intervention compared to baseline.

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C. MAIN SECTION OF THE PROPOSAL

1. OVERALL GOALS AND OBJECTIVES. The overall goal is to investigate the effectiveness of motivational interviewing (MINT) as a behavioral intervention to improve medication adherence as part of an established patient-centered disease management program for patients with rheumatoid arthritis (RA).

Our key objectives are two-fold:

1) We expect to identify patient-specific concerns and barriers regarding medication adherence that will be addressed via motivational interviewing;

2) We anticipate improvement in medication adherence associated with a motivational interviewing intervention as part of an ongoing systematic disease activity management program for RA patients.

Using the self-determination theory of health behavior as our conceptual framework, we will evaluate the effect of motivational interviewing (MINT) as part of a patient-centered intervention to improve medication adherence. ***We propose a non-randomized single intervention study to determine whether MINT can improve RA medication adherence.*** This study will leverage the large RA population across the NYU campus, with our established patient-centered RA disease management program and clinical research infrastructure. We will perform MINT on 200 RA patients with inadequately controlled RA disease activity (moderate or high disease activity) who are receiving at least one oral disease modifying anti-rheumatic medication (DMARD). A major strength of this proposal is that the infrastructure for routine RA disease activity monitoring at all clinic visits (to identify those with moderate/high disease activity) using the multi-dimensional health assessment questionnaire (MDHAQ) to calculate RAPID3 disease activity scores is already implemented. The established infrastructure and large patient population will streamline appropriate recruitment into the study. All MINT counseling sessions will be administered monthly by telephone over the 6 month intervention duration.

Primary Aim. To evaluate the effectiveness of motivational interviewing (MINT) to improve medication adherence in RA patients prescribed oral DMARD(s).

> ***Hypothesis.*** **The MINT intervention will positively influence the patient, in terms of modifying both medication beliefs and medication adherence self-efficacy, which we hypothesize will improve oral DMARD medication adherence at 6 and 12 months.**

Exploratory Aims:

1) To evaluate the relationship of change in medication beliefs and self-efficacy (due to MINT) with change in medication adherence.

2) To examine the relationship of change in medication adherence with change in patient-reported outcomes including pain, functional status and a composite measure of RA disease activity (RAPID3) over the short-term (6 months) and longer term (12 months).

2. TECHNICAL APPROACH.

Published studies on rates of adherence to RA medications vary widely, but there is consensus across studies that adherence rates are suboptimal (1;2). In particular, RA medication nonadherence has been reported to be worse in racial and ethnic minority RA cohorts, and linked to higher RA disease activity and worse radiographic damage (3-5). **Consistent with previous research, our pilot study of RA patients from the NYU-affiliated clinics with a diverse racial/ethnic population indicates that medication nonadherence is a major problem in our local RA population, and that adherence is linked to a potentially modifiable set of factors including medication beliefs and medication adherence self-efficacy.** The intervention for the proposed study – motivational interviewing (MINT) – is an empirically validated behavioral intervention that we hypothesize will improve RA medication adherence by modifying medication beliefs and medication adherence self-efficacy. To our knowledge, this is the first U.S.-based implementation study of motivational interviewing in RA patients. We conducted an extensive literature search, identifying a single study incorporating group-based MINT in a European academic center (6).

This initiative builds upon a ***pre-existing and active*** multidisciplinary collaboration between the NYU Division of Rheumatology and the NYU Center for Healthful Behavioral Change (CHBC). The NYU CHBC has a proven track record of large NIH-funded implementation studies of motivational interviewing across chronic diseases. The project team will be led by a clinical rheumatologist and epidemiologist as PI (Jeff Greenberg, MD, MPH), in close collaboration with Dr. Yusuf Yazici (Co-I), an experienced rheumatologist who has already successfully implemented the RAPID3 RA disease activity management system across the NYU clinics using the MDHAQ. To develop a more comprehensive disease management program that directly addresses medication adherence, we have developed a successful multidisciplinary collaboration between Dr. Greenberg's research team and Dr. Olugbenga Ogedegbe [Director, Center for Healthful Behavior Change (CHBC) at NYULMC] and two behavioral scientists on the CHBC faculty, Dr. Antoinette Schoenthaler and Dr. Tanya Spruill. ***Dr. Ogedegbe and his team bring extensive experience in implementation of behavioral interventions including MINT to improve medication adherence in patients with chronic diseases.*** In particular, Drs. Ogedegbe and Schoenthaler have successfully implemented and published their work on a similar MINT intervention to improve medication adherence to antihypertensive medications in the African American population (NIH Grants R01HL69408, R01HL087301) (7-9). Further, Drs. Greenberg, Ogedegbe and Spruill were funded by the NYU-HHC CTSI to conduct the pilot projects supporting this application. Results of the first pilot collaborative study on the relationship of RA medication adherence with medication beliefs and adherence self-efficacy are currently in press (Spruill T et al., *Annals of Rheumatic Diseases* 2013) (10).

a. CURRENT ASSESSMENT OF NEED IN TARGET AREA

i) PROJECT STARTING POINT AND QUANTITATIVE BASELINE DATA SUMMARY

In this collaborative study between the NYU Division of Rheumatology (Dr. Greenberg) and the

CHBC (Drs. Spruill and Ogedegbe), we examined determinants of RA medication adherence as part of a NYU CTSI-funded study **(NIH grant #5UL1RR029893)** in the NYU-affiliated arthritis clinics. Our objectives were twofold: 1) to estimate the prevalence of RA medication nonadherence; and 2) to identify factors associated with nonadherence in our local clinic population.

A sample of 50 RA patients recruited from the NYU Hospital for Joint Diseases Arthritis Clinic and the Bellevue Hospital Arthritis Clinic completed this cross-sectional study. We administered the validated Morisky medication adherence scale, as well as questionnaires on RA medication beliefs and medication self-efficacy.

Patient demographics were typical of an RA population (92% female, mean age 52.5 ± 12.3 years). Patients completed self-report questionnaires including the **Morisky medication adherence scale** (8 items); the **Medication Adherence Self-Efficacy Scale (MASES)**, which we adapted for RA (20 items); and the **Beliefs about Medicines Questionnaire (BMQ),** which includes two subscales: beliefs about the necessity of medications (5 items), and concerns about medications (5 items). Sample items from each of these scales are shown in **Table 1**.

Table 1: Sample items from the BMQ-Necessity, BMQ-Concerns and MASES (self-efficacy)

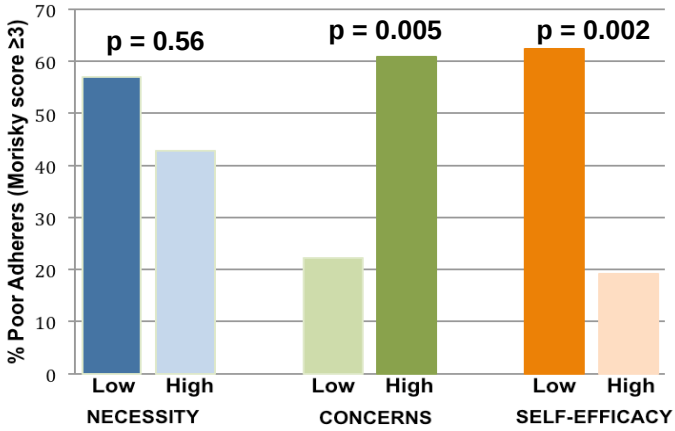
BMQ: Beliefs about necessity of medications:
My health, at present, depends on my medicines.
My medicines protect me from becoming worse.
BMQ: Concerns about medications:
Having to take medicines worries me.
I sometimes worry about the long-term effects of my medicines.
MASES (self-efficacy): How confident are you that you can take your RA medications…
…when you don't think they are helping.
…when you do not have symptoms.

Overall, self-reported medication adherence in our local NYU clinic populations was fairly poor; ***78% of patients endorsed at least one problem with adherence on the Morisky scale and 40% were classified as poor adherers*** (i.e., 3 or more adherence problems). Although we did not use the same method for estimating medication adherence as Waimann et al. in a recently published study, the extent of nonadherence in our population reinforces the observations by Waimann et al from an urban minority population that used medication electronic monitoring (5). In our study, individual adherence questionnaire items revealed that 44% of patients sometimes forget to take their medications and 30% did not take their last scheduled dose.

We also examined factors associated with RA medication adherence. Of particular importance, ***worse medication adherence was significantly associated with both lower self-efficacy (r=-0.63, $p<0.001$) and higher concerns about medications (r=0.50, p=0.01),*** but was not related to beliefs about the necessity of medications (r=-0.10, p=0.55). **Figure 1** shows the percentage of patients classified as poor adherers (Morisky score ≥3) according to medication beliefs and self-efficacy (High vs. Low based on median splits of beliefs and self-efficacy scores).

As shown in *Figure 1*, almost three times as many patients with high medication concerns were poor adherers compared with those with low concerns (60.9% vs. 22.2%, χ^2=7.73, *P*=0.005)**. We also found that more than three times as many patients with low self-efficacy were poor adherers compared with those with high self-efficacy** (62.5% vs. 19.2%, χ^2=9.74, *P*=0.002).

Figure 1. Rates of poor adherence by medication beliefs and self-efficacy (N=50).



These preliminary studies support our hypothesis regarding the relationship of medication adherence with adherence self-efficacy and medication beliefs in RA patients, and suggest these may be effective intervention targets for improving adherence. Furthermore, our results reinforce the findings of a recent systematic review of the literature (18 high quality studies) that reported that patient beliefs about medications are one of the major determinants of medication adherence in RA patients (11). Our manuscript reporting these findings is currently in press (Spruill et al, *Annals of Rheumatic Diseases*, 2013) (10).

MINT Feasibility Pilot Study. A second pilot study (PI Greenberg) focusing specifically on the feasibility and patient acceptance of motivational interviewing for RA patients is currently underway. We have nearly completed enrollment (25 of 30 projected patients enrolled). Among the 25 patients enrolled, 22/25 (88%) remain active participants in the 6-month MINT telephone-based intervention, with positive feedback to our research team. Three (12%) of the enrolled patients have dropped out, consistent with our experience with MINT in other chronic conditions. We anticipate completion of the pilot by December 2013.

ii) PRIMARY AUDIENCE AND OTHERS WHO WILL BENEFIT

The primary audience for our motivational interviewing is the ***RA patient population in our clinics***. We also anticipate that the successful demonstration of the effectiveness of incorporating MINT as part of clinical care will stimulate broader adoption of MINT by ***other U.S. rheumatologists*** to improve medication adherence.

b. INTERVENTION DESIGN AND METHODS.

Rationale for Motivational Interviewing to Improve RA Medication Adherence: Motivational interviewing (MINT) is a well-known, empirically supported intervention originally developed for the treatment of alcohol addiction (12); its use has since expanded to other areas of behavior change, including treatment adherence (13). MINT is guided by the *self-determination theory of behavior change* (14). This theory is defined as a patient-centered counseling approach that encourages patients to express their concerns about and barriers to taking

medications, connect their personal values and goals to their health behaviors, enhance motivation and confidence for change, and commit to behavior change. *Thus, MINT directly addresses both medication beliefs and self-efficacy perceptions, the two hypothesized mechanisms underlying suboptimal medication adherence in RA patients based on our preliminary studies.* MINT is guided by five basic principles: ***1)*** expressing empathy; ***2)*** developing discrepancy between patients' goals and current problem behavior; ***3)*** avoiding argumentation; ***4)*** "rolling with resistance" rather than confronting or opposing it; and ***5)*** supporting self-efficacy and optimism for change rather than been judgmental. Two key skills used in MINT are reflective listening and eliciting self-motivational statements, which encourage the development of ambivalence or discrepancy about the patient's present behavior and future goals and values, and enhance motivation for behavior change.

Positive effects of MINT on medication adherence, health behaviors and quality of life have been demonstrated in various chronic disease populations, including for hypertension by Dr. Ogedegbe (Co-I) (7;15;16). For example, Dr. Ogedegbe conducted a clinical trial comparing MINT versus usual care in 190 hypertensive African Americans, and found positive effects of MINT on medication adherence and systolic blood pressure over a 12-month study period (7). Despite the utility of this counseling approach, and empirical evidence of its effectiveness in improving medication adherence across chronic diseases, MINT has never, to our knowledge, been evaluated as an intervention to improve medication adherence in RA patients. *As depicted below in the conceptual framework in **Figure 2**, we hypothesize that patients undergoing motivational interviewing will experience increased self-efficacy and increased positive medication beliefs, resulting in improved medication adherence.*

Figure 2.
Conceptual framework for Motivational Interviewing to Improve Medication Adherence.

Description of MINT Protocol for Implementation.
All patients who agree to participate will receive monthly telephone-based MINT counseling sessions for 6 months. Each MINT session will be conducted with the aid of a standardized structured adherence counseling script. The use of a standardized adherence counseling script was initially developed for use in medication adherence studies of HIV positive patients (17), which Dr. Ogedegbe and his team adapted for use in hypertension patients (7;8). For our MINT feasibility study in RA patients, Dr. Ogedegbe and his team have further adapted the MINT script and overall protocol for RA patients. Specifically, the MINT Counselor (Mr. Castillo) has been trained to discuss patients' current RA symptoms and functioning, medication adherence (e.g., issues surrounding both oral and injectable medications), and other factors relevant to RA

patients' overall quality of life. Importantly, the Counselor has also been trained to refer patients back to their physicians for any specific medical questions.

After establishing rapport with the patient on each telephone call, the Counselor (non-physician) will go through the following sequential steps which will be described in detail in the counseling script: ***1)*** assess the patient's motivation and confidence regarding medication adherence; ***2)*** elicit barriers, concerns and positive self-motivational statements about their adherence behavior; ***3)*** summarize patient-generated "pros" and "cons" of adhering to prescribed medications; ***4)*** discuss potential solutions to identified barriers; ***5)*** develop a behavioral contract to try at least one of the solutions identified; and ***6)*** summarize the session. Although the basic structure of the intervention will be consistent across participants, session content will be tailored to the individual.

MINT Training and Treatment Fidelity: The MINT Counselor (Patricio Castillo) is trained and certified as a MINT counselor, and has collaborated on the pilot study this past year. Similar to our procedures across all our other studies, the Counselor will attend two 8-hour training sessions (which include lectures and supervised role-plays) led by Dr. Schoenthaler during the start-up phase of the study and a 1-day booster training session yearly thereafter to minimize decay. To maximize the quality and consistency of the intervention, all MINT sessions will be digitally audiotaped. Dr. Spruill will review 20% of the tapes to facilitate ongoing feedback and supervision of the Counselor during the study. In addition, Dr. Schoenthaler will code the tapes to document treatment fidelity using the Motivational Interviewing Treatment Integrity (MITI) scale (18), which we have used in other studies of MINT conducted at CHBC.

Patient Compliance: Based on our feasibility study, we will utilize the following strategies to ensure an optimal level of patient compliance: ***1)*** at enrollment we will stress the importance of completing the telephone sessions, and the value of these sessions for the patient; ***2)*** the Study Coordinator will place reminder telephone calls to patients on the day or evening prior to the date of each scheduled telephone session; ***3)*** the Counselor will be flexible in accommodating patients' schedules (including weekend availability) to minimize missed sessions.

STUDY VISITS TO RHEUMATOLOGIST:

Baseline Visit: Data elements collected at baseline, as well as Month 6 and Month 12 are summarized in Table 2, below. All demographic information, DMARD medication use and RAPID-3 disease activity information, are collected as part of routine care using the MDHAQ Form. In addition, at baseline and after 6 months, we will administer the BMQ (Beliefs about Medicines Questionnaire) and the Medication Adherence Self-Efficacy (MASES-RA) questionnaire. In addition, after obtaining consent at the baseline visit, a one-page additional form will be completed by the patient with the patient's pharmacy information to collect prescription refill information (to calculate MPR values) to study medication adherence.

Follow-up Visits (6 months and 12 months): Unlike a standard RCT, the follow-up visits will not be mandated at precise time points, but rather will follow standard of care clinic appointments. Thus, we will apply time windows after a period of 6 months and 12 months to

calculate change in RAPID3 disease activity values, as well as perform the follow-up BMQ and MASES-RA questionnaires (6 months). Because the MDHAQ is performed at all clinic appointments, we expect this approach will be easily implemented, as we have observed in our pilot study.

TABLE 2 – Schedule of Study Procedures and Visits

	Procedure	Screen/ Baseline	Mo 1	Mo 2	Mo 3*	Mo 4	Mo 5	Mo 6	Mo 12
Rheumatologist office	Consent	X							
	Review Inclusion/ Exclusion criteria	X							
	Multidimensional Health Assessment Questionnaire (MDHAQ)	X			X*			X	X
	RAPID3 score calculated by physician based on MDHAQ	X			X*			X	X
	Physician Rx data of DMARDs based on MDHAQ	X			X*			X	X
	Beliefs about Medicines Questionnaire	X						X	
	Medication Adherence Self-Efficacy Scale (MASES-RA)	X						X	
Pharmacy FAX	Pharmacy refill data (primary records)	X						X	X
MINT Counseling	Motivational Interview (MINT) conducted by MINT Counselor over the telephone	X	X	X	X	X	X	X	

*The MDHAQ is performed at all routine clinic visits. Month 3 is included as an example.
Note: The completion of the MDHAQ will allow calculation of the RAPID3 disease activity score, patient physical function score (alone) from the MDHAQ, and patient pain (VAS). It also collects detailed information on all DMARDs being taken at the time of the visit.

c. EVALUATION DESIGN

i. DETERMINATION THAT THE IDENTIFIED PRACTICE GAP IS ADDRESSED IN TARGET GROUP

DMARD adherence. The primary outcome that we will assess will be the calculated Medication Possession Ratio (MPR). The MPR will be calculated from pharmacy prescription fill data, collected from each patient's pharmacy as implemented in our ongoing pilot MINT feasibility study and other trials of medication adherence (19). Although no measurement tool of medication adherence is without limitations, MPR calculations using refill data have been widely used by Dr. Harrold (Consultant) and others to assess medication adherence of rheumatic disease medications. The MPR will represent the proportions of days' supply that

were filled over the 6-month (and 12-month) period. We will calculate the MPR by dividing the aggregated number of days supply of prescription filled over the number of possible days for the 6-month (and 12-month) period taking into account the date of enrollment and study time period. We will calculate MPR values at baseline for a 6-month period prior to enrollment, and then at 6 months and 12 months for the 6-month intervals since enrollment.

- **Sources of data.**

1) Pharmacy Refill Data. For the trial, after patients have provided informed consent, the Study Coordinator will contact each patient's pharmacy at baseline, 6 and 12 months to obtain and update the patient pharmacy data on prescription fills for DMARDs. Prescription refill data will be analyzed as individual DMARDs, as well as categorized as oral DMARDs versus SQ and IV DMARDs. We will send a fax to each pharmacy, requesting that the prescription fill data be faxed back to us. The fax machine will be kept in a secure area. The returned data will be entered into the study database, as implemented in our ongoing pilot feasibility study.

2) Multi-Dimensional Health Assessment Questionnaire (MDHAQ). The MDHAQ questionnaire is currently administered to all RA patients at all rheumatology clinic appointments. This standardized dataset, therefore, will be available for data analysis in a streamlined manner with no additional patient burden. We will therefore have access to: **1)** patient demographics, comorbidities; **2)** DMARD use including dose and frequency; **3)** RA disease activity level using the RAPID3 (Routine Assessment of Patient Index Data3); **4)** Patient pain score (visual analogue scale); **5)** Patient physical function score (alone) from the MDHAQ. A key feature of this project is that the RAPID3 (completed by patients prior to each routine visit) will be used to screen patients for eligibility with moderate or high disease activity using published RAPID3 cutpoints for moderate and high disease activity (20).

3) Additional Patient Questionnaires.
At baseline after enrollment and at the study completion (6 months), we will collect additional data from two validated questionnaires of medication beliefs and self-efficacy that we have adapted and implemented in our two pilot studies. Based on our preliminary results, we anticipate that our understanding and measurement of medication adherence self-efficacy and beliefs about medications will enhance our study for the exploratory aim to understand mediators of medication nonadherence:

a) The Medication Adherence Self-Efficacy Scale (MASES-R) is a valid and reliable measure of medication adherence self-efficacy (21;22) developed by Dr. Ogedegbe (Co-I) for hypertension that we have adapted for RA. Patients are asked to rate their confidence in taking their medications under a variety of situations that may pose difficulties. The adapted MASES-R includes 20 items rated on a 4-point Likert scale and was associated with medication adherence in our pilot RA study results [see Section A above] (10).

b) The Beliefs about Medicines Questionnaire (BMQ) (23) will be used to assess two dimensions: ***1)*** patients' beliefs about the necessity of prescribed RA medications, and ***2)*** their concerns about the potential consequences of taking the medications. The BMQ

includes 10 items that are rated on a 5-point Likert scale. This measure has been validated in chronic disease populations (24) and has been associated with treatment adherence in RA patients both in the literature (25;26) and in our pilot RA study results [see Section A above] (10).

- **Analysis Plan.**

The proposed research is a longitudinal, single intervention ***quality improvement project*** with the primary aim of evaluating the effect of MINT on oral DMARD medication adherence. As defined in the Pfizer RFP, we will categorize each patient's adherence in a dichotomous fashion, both at baseline and at study completion, using the MPR cutpoint of 0.80 to define adherence versus nonadherence. We will calculate the proportion of patients with MPR >0.80 at baseline and 6 months to determine the proportion of patients who improved from being nonadherent (MPR<0.80) to adherent (MPR >0.80). We will use the *McNemar test* to test for a statistically significant difference between paired proportions. The McNemar test is frequently used in studies in which patients serve as their own control, including quality improvement projects with "before and after" study designs. We will also examine 12-month change in the proportion of adherence patients to assess the degree to which effects of MINT are sustained after completion of the 6-month intervention.

ii. QUANTIFICATION OF CHANGE AFTER INTERVENTION.

Power and Sample Size.

Although formal power calculations are not always used for quality improvement projects, we performed power calculations to address concerns of adequacy of sample size. The sample size partly depends on the proportion of discordant pairs observed in the 2x2 contingency table of paired results for dichotomized adherence rates comparing proportions (before versus after). Assuming a sample size of 200 patients and discordance of 0.1 with alpha of 0.05, with the proportion of patients at baseline with good adherence (MPR>0.80) of 65% [as reported by Harley et al from a large U.S. cohort study for methotrexate (27)], we will have > 80% power to detect a change in the proportion of adherent patients improving by 6% or greater at study completion (post-intervention adherence rates of 71% or greater). Using a more conservative discordance assumption of 0.2 with 200 patients, we would still have >80% power to detect an improvement of 9% or greater. We expect a 10% to 15% improvement in medication adherence based on prior studies and the work by Dr. Ogedegbe in hypertension medication adherence (7;16).

Of note, in a systematic review of MINT studies, the mean number of subjects was N=198 (13). Based on our power calculations, we anticipate that our proposed sample size of 200 patients should have adequate power. Power and sample size estimates for testing correlated proportions using McNemar's test were generated using PASS 12 (28).

iii. TARGET AUDIENCE ENGAGEMENT.

We will evaluate the engagement of the target audience using two primary approaches. First, we will monitor the percentage of planned MINT counseling sessions completed, and will assess

whether compliance differs by important demographic or clinical characteristics. Second, we will conduct post-study debriefing interviews with all patients to assess their satisfaction with the program and gather feedback for improvement.

iv. DISSEMINATION PLANS.

We plan to present our study results at national and international meetings, followed by a full-length manuscript publication after study completion. Specifically, we anticipate presentation of the study results at the American College of Rheumatology (ACR) annual meeting, the European League Against Rheumatism (EULAR) annual meeting and the Society of Behavioral Medicine annual meeting.

3. DETAILED WORK PLAN AND DELIVERABLES SCHEDULE

PROJECT TIMELINE. The planned performance period is 34 months (October 1, 2013 through July 31, 2016). Study set-up activities will occur in Months 1-3. Patient enrollment will occur in Months 4-16. Patient assessments, interventions and follow-up will occur in Months 4-22. Study completion for the final study participant will be in Month 22. Data analysis will occur in Months 23-30. Abstract/manuscript preparation and submission will occur in Months 26-34. A graphic illustration of deliverables and costs associated with this timeline is presented in Table 3, below.

WORK PLAN:

- **Months 1-3: Study set-up**

  Finalized protocol and IRB approval [Deliverable 1]: Dr. Greenberg, in close collaboration with Co-Investigators, will fine-tune and finalize the study protocol, and obtain IRB approval of the project.

  Development/finalization of Motivational Interviewing (MINT) telephone script [Deliverable 2]: Dr. Greenberg, in close collaboration with Drs. Schoenthaler and Yazici in particular, will develop and finalize the Motivational Interviewing (MINT) telephone script. Dr. Schoenthaler will develop the motivational interviewing training curriculum.

- **Months 4-16: Patient recruitment/enrollment** [Deliverable 3]: Drs. Greenberg and Yazici, and Study Coordinator/Project Manager Ms. Alvarado, will recruit/enroll 200 study participants over Months 4-16.

- **Months 4-22: Patient assessments, interventions and follow-up**

  Patient visits/Data collection [Deliverable 4]: 200 patients will be seen at visits as detailed in Table 2, above. Drs. Greenberg and Ms. Alvarado will oversee collection of questionnaire data, with assistance from Dr. Yazici.

  Training of MINT Counselor in interview protocol specific to project [Deliverable 5]: The Counselor will attend two 8-hour training sessions (which include lectures and supervised role-plays) led by Dr. Schoenthaler during the start-up phase of the study and a 1-day

booster training session yearly thereafter to minimize decay.

Patient interventions/MINT counseling [Deliverable 6]: Beginning in Month 5 and continuing through Month 22, Mr. Castillo (MINT Counselor) will conduct 6 monthly telephone interview sessions per patient for 200 patients. Ms. Alvarado will be responsible for tracking of the follow-up with the MINT counselor.

Treatment fidelity validation for MINT counseling [Deliverable 7]: To maximize the quality and consistency of the intervention, all MINT sessions will be digitally audiotaped. Dr. Spruill will review 20% of the tapes to facilitate ongoing feedback and supervision of the Counselor during the study. In addition, Dr. Schoenthaler will code the tapes to document treatment fidelity using the Motivational Interviewing Treatment Integrity (MITI) scale (18)

Assessment of medication adherence (MPR) from pharmacy records [Deliverable 8]: After patients have provided informed consent, Ms. Alvarado (Study Coordinator) will contact each patient's pharmacy at baseline, 6 and 12 months to obtain and update the patient pharmacy data on prescription fills for DMARDs. Prescription refill data will be analyzed as individual DMARDs, as well as categorized as oral DMARDs versus SQ and IV DMARDs. We will send a fax to each pharmacy, requesting that the prescription fill data be faxed back to us. The fax machine will be kept in a secure area. The returned data will be entered into the study database. Dr. Harrold (Consultant) will provide expertise in developing the protocol and procedures for evaluating medication adherence, and guide the statistical analyses for evaluating medication adherence. She will collaborate with Dr. Greenberg to create the data extraction procedures from the pharmacy refill records for calculating medication adherence (Medication Possession Ratio).

Study completion for the final study participant will be in Month 22.

- **Months 23-30: Data analysis** [Deliverable 9]
  The Study Biostatistician will perform the data analysis, working closely with the study team: Dr. Greenberg, PI; Drs. Ogedegbe, Spruill and Yazici, Co-Investigators; and Dr. Harrold, Consultant. During the data analysis phase, Ms. Alvarado (Study Coordinator/Project Manager) will continue to maintain datasets and assist in making them available to the PI, Biostatistician and Co-Investigators.

- **Months 26-34: Abstract/manuscript preparation and submission** [Deliverable 10]: Dr. Greenberg, PI, will take the lead in preparation of abstracts and manuscripts reporting the study findings, working closely with Dr. Spruill who will also play a major role in drafting reports. Drs. Ogedegbe, Yazici and Harrold, and the Biostatistician, will also contribute to the analysis and interpretation of the results.

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