Standardized Versus Tailored Implementation of Measurement-Based Care for Depression

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A. SPECIFIC AIMS

Depression remains among the top ten chronic illnesses, costing $83 billion annually (Greenberg, et al., 2003). Numerous efficacious psychotherapies exist (e.g., Cognitive Behavioral Therapy; Butler et al., 2006), but are relatively unavailable in community mental health settings. Implementation of these complex psychotherapies is resource-intensive (Clark, 2011) and sustainment is rare (Stirman, et al., 2012). Measurement-based care (MBC; i.e., routine measurement of client symptoms on which care decisions can be made) is a highly accessible evidence-based framework (Lambert et al., 2003; Scott & Lewis, *in press*) that enhances usual care psychotherapy by increasing the number of treatment responders and decreasing rates of deterioration (Bickman et al., 2011; Whipple, et al., 2003). *Simply providing clinicians (i.e., mental health counselors) with symptom scores improves outcomes.* We contend that MBC can be the minimal intervention needed for change (Glasgow et al., 2013). Unfortunately, fewer than 20% of community clinicians use MBC (deBeurs et al., 2010) due to perceived barriers such as time and feasibility (Garland, Kruse, & Aarons, 2003). Tailored implementation (in which strategies are designed to target determinants of practice revealed through careful assessment; Wensign, Bosch, & Grol, 2010) is touted as the optimal approach (Grol & Grimshaw, 2003). Moreover, it is possible that tailoring MBC protocols to the site may optimize sustainment (Chambers, Glasgow, & Stange, 2013). However, no studies, to our knowledge, have directly compared standardized and tailored approaches, revealing a critical gap in the implementation literature and the potential for high impact results.

We propose a randomized trial of standardized versus tailored MBC implementation in Centerstone, one of the nation's largest not-for-profit community mental health centers. This proposal builds on a 2-year academic-community partnership in which the *long-term goal* is to introduce MBC across 100+ sites. This hybrid type 2 design will assess both implementation (clinician-level; MBC fidelity) and intervention (client-level; depression severity) outcomes. We have the unique opportunity to evaluate MBC implementation, as Centerstone will have recently introduced a new electronic health record (EHR) system. The implementation protocol is informed by our 2-site pilot study in which MBC achieved 67% penetration. The Patient Health Questionnaire (PHQ-9; Kroenke, 2001) will be embedded in the EHR using tablet computer client data capture. Both conditions will use a blended implementation protocol of the best available evidence-based strategies to ensure equal access to resources, including (a) a needs assessment, (b) formation of an implementation team, (c) MBC use guidelines, (d) training, and (e) triweekly group consultation. Mendel et al.'s (2008) *Framework for Dissemination* will guide evaluation (needs assessment, implementation, and outcome evaluation). This framework will also be used to tailor training and consultation content to target barriers identified in the needs assessment (contextual factors, e.g., attitudes); the standardized condition content is set *a priori*. In the tailored condition, the implementation team will establish the MBC use guideline (e.g., monthly administration), whereas the standardized condition guideline will require routine administration prior to each session with a depressed client (Lambert et al., 2003). This design will test the Dynamic Sustainability Framework (Chambers, et al., 2013), as sites in the tailored condition will adapt MBC guidelines to fit their context. MBC fidelity (range 0-3; client completed=0/1; clinician reviewed=0/1, scores discussed=0/1) and reasons for deviations (e.g., lack of time) will be monitored via EHR enhancements; clients will also report on clinician discussion of scores.

Phase I: Pre-Implementation (Months 0-8). The PHQ-9 and fidelity measures will be embedded in the EHR and the PHQ-9 linked to tablet computers for client completion to promote feasibility. *Phase 2: Randomized Implementation Trial: Dynamic Waitlist Control* (Months 8-38; Sites: *N*=12; Clinicians: *N*=150; Clients: *N*=500; mixed within- & between-subjects design). MBC implementation will occur across 4 cohorts (2-4 sites) at early and later stages (each with 5-months active implementation, 10-months sustainment) to reduce confounds (timing) and increase feasibility (phased training). Both conditions will enact the 5 strategies within the active implementation period. We will use rapid ethnography (month 1) to synthesize the needs assessment data and develop the tailored content. *Phase 3: Characterization of MBC Fidelity* (Months 38-48). MBC fidelity will be coded, clinician and client fidelity reports will be triangulated, and sustainment will be evaluated.

Specific Aims. The hybrid design yields *one co-primary aim* (outcomes at the clinician- and client-levels) and *two secondary exploratory aims* in the context of a pragmatic trial (Thorpe et al., 2009).

Aim 1: To compare the effect of standardized versus tailored MBC implementation on clinician-level (**1a**) and client-level (**1b**) outcomes. We hypothesize that tailored implementation will outperform standardized in terms of (**H1a**) MBC fidelity, and (**H1b)** reducing client depression severity.

Aim 2: To identify contextual mediators of MBC fidelity. We hypothesize (**H2**) that contextual mediators (structure, norms, etc.) will be leveraged in the tailored condition, but serve as barriers in the standardized condition.

Aim 3: To explore the impact of MBC fidelity on client outcomes (Chambers et al. 2013). We hypothesize (**H3**) that adapted MBC protocols (tailored condition) will outperform weekly administration of PHQ-9s (standardized condition) with respect to clinically significant change in depression severity from intake to week 12.

B1. SIGNIFICANCE

The long-term goal of this research project is to provide generalizable and practical recommendations about implementation approaches that promote Measurement-Based Care (MBC) use and effectiveness in community mental health centers, a goal developed in partnership with stakeholders at Centerstone. Previous attempts to integrate MBC into real world settings have focused on the development of standalone feedback systems (Koerner, Dailey, Lipp, Connor, & Sharma, 2012; Sapyta, Riemer, & Bickman, 2005). However, to our knowledge, no studies have investigated the strategies necessary to integrate MBC into community mental plementation support or (b) taking into account stakeholder perceptions and needs when building the implementation approach. This proposal reflects the ideas generated by a 2-year academic-community partnership between the proposal PI (Lewis), Centerstone Research Institute Director (Co-I, Ayer) and regional clinic directors whom constitute our advisory board (Drs. Harrison, Hardy, Pardue, Moran, Marshall; *Letters of Support*).

The proposed implementation of MBC by community mental health clinicians who treat depression is *significant* because despite decades of research revealing numerous efficacious treatments for depression, this disease remains among the top ten chronic diseases in the nation (Greenberg et al., 2003). Moreover, MBC is an evidence-based framework that has established **effectiveness**, broad **reach**, and multifaceted **utility** for enhancing usual care. MBC presents a simple framework in which care is based on the results of symptom measurement. A meta-analysis indicated that MBC is particularly **effective** in improving outcomes when depressed clients are not demonstrating progress (Shimokawa, Lambert, & Smart, 2010) and by reducing client deterioration (Lambert, et al., 2003) with medium effect size improvements over usual care (Bickman et al 2011; Whipple, et al., 2003). MBC has greater **reach** potential than complex Evidence-Based Practices (EBP) that include multiple theory-specific components targeted at single disorders; MBC is a simple standalone practice framework that increases the effectiveness of diverse usual care offerings for clients with multiple problems. MBC may be the "*minimum intervention needed for change"* (MINC; Glasgow et al., 2013). The reach of MBC is particularly strong because its relevance is transtheoretical (relevant for use by clinicians regardless of background) *and* transdiagnostic (effective in enhancing usual care for numerous disorders) (Scott & Lewis, *in press*). MBC's **utility** is multifaceted and aligns with the Affordable Care Act by focusing on monitoring outcomes. MBC presents a systematic approach for selecting and adapting interventions (Trivedi & Daly, 2007); it flags clients who are not improving; and, it highlights treatment targets (Lambert et al., 2005). NIMH's nationwide public health clinical trial, the STAR*D (Sequenced Treatment Alternatives to Relieve Depression), demonstrated MBC's utility for guiding both medication and psychotherapeutic interventions (Trivedi et al., 2006). MBC also has established utility for promoting care coordination across disciplines (Unutzer et al., 2002). MBC provides the basis for evaluating subsequent EBP implementation efforts through a foundation of progress monitoring, which leverages the soon to be ubiquitous electronic health record technologies.

By design, MBC has great potential for implementation success, yet barriers such as attitudes (perceptions that standardized measures have limited utility) and feasibility (perceptions that measures take too much time) exist (Garland et al., 2003), and the gap between documented MBC effectiveness and use in practice remains. Research to date has largely focused on evaluating standardized approaches to implementation, despite a recent Cochrane meta-analysis highlighting the potential impact of tailoring implementations (Baker et al., 2009). There is a crucial need for process-focused implementation research. Hence our proposed comparison of implementation conditions (i.e., standardized versus tailored) is *both clinically and scientifically significant* because it will (a) reveal whether standardized or tailored approaches to implementation optimize MBC fidelity, (b) enhance our understanding of both theory and processes for standardized versus tailored implementation; and, (c) illuminate predictors, moderators, and mediators of successful implementation. Our proposed implementation-effectiveness hybrid design will yield important insights regarding MBC clinician level implementation outcomes. It will simultaneously shed light on the effect of MBC on adult mental healthcare for depression in

community settings when adapted by stakeholders to fit their context. Our research will answer the *how* of implementation by evaluating the effect of contextual factors on the process, an effort that directly aligns with NIMH's Strategic Plan 4.1 to "Improve understanding of the factors that affect…the means by which newly discovered effective mental health interventions are disseminated and implemented."

B2. INNOVATION. *This proposal is innovative in at least three ways.*

1) Minimal Intervention Needed for Change (MINC; Glasgow et al., 2013)**.** Our focus on testing strategies to implement MBC in community mental health is innovative because this simple MBC framework may be the minimal intervention needed for significantly reducing the burden of depression on society. For the treatment of depression, we opted to focus on MBC rather than a complex, theoretically-driven EBP like Cognitive Behavioral Therapy not only because of the MBC implementation gap, but also because the simplicity and accessibility of the MBC framework will reduce the number of implementation barriers. Moreover, MBC has been isolated as a core component of many of EBPs. Therefore, identifying effective implementation strategies for MBC would build the case for a phased or staged approach to full package EBP implementation to determine whether later EBP implementations enhance outcomes beyond improvements observed with MBC.

2) Leveraging Low Cost Technology. We will use tablet computers linked to an online MBC platform that is embedded within the electronic health record system. The use of technology will decrease the time burden of MBC and will enhance the utility it brings to clinicians, clients, the organization, and research (Powell et al., 2005). The tablets' high-tech features have the potential to promote client engagement in treatment and may help to emphasize the importance of symptom monitoring. Linking the tablet data collection with the electronic health record will also allow us to build useful, innovative features such as symptom trajectory graphs, alerts when suicidality is endorsed, and ideas/suggestions for treatment targets. With electronic health record prevalence increasing and tablet computer costs decreasing, this approach presents a generalizable and cost-effective method for engaging in systematic outcome monitoring that maximizes therapeutic benefit.

3) Tailored Implementation. The majority of existing implementation research has focused either on descriptive studies that explore barriers and facilitators (determinants of practice) *or* on comparisons of *a priori* selected implementation strategies that generally neglect contextual tailoring of the interventions. A qualitative analysis of 22 implementation studies revealed that few focused on matching strategies to deteminants of practice (Bosch, van der Weijden, Wensing, & Grol, 2007). A critical research agenda has emerged seeking to identify, "how and why implementation processes are effective" (Proctor, Powell, Baumann, et al., 2012) by experimentally evaluating implementations that are tailored to the context. Table 1 summarizes the conceptual differences between standardized and tailored conditions in this proposal.

Table 1. Implementation Conditions

Standardized	Tailored
M**anualized** implementation content	Content adapted by implementation team to address barriers
Developed *a priori*	Responsive to local needs
Standardized MBC guide-	MBC administration set by site

Tailored Implementation and Quality Improvement approaches overlap with respect to their ultimate goal of improving client care through changing provider behavior using context-specific strategies. However, *Tailored Implementation and Quality Improvement differ in three key ways*. One, Quality Improvement focuses primarily on change as it occurs outside of the intervention whereas Tailored Implementation allows for changes to the intervention to fit the context (Chambers, Glasgow, & Stange, 2013). Recent findings support the need to adapt evidence-based practices during the implementation process (Aarons, Miller, Green et al., 2014; Stirman, et al., 2013), but no studies have directly compared this approach to standardized EBP implementation. Two, Quality Improvement engages the Plan-Do-Study-Act as a means for identifying necessary change strategies driven by data in a cyclical fashion, whereas Tailored Implementation begins with a needs assessment to identify context-specific determinants of practice and then adapts implementation content to match determinants of practice. Three, implementation is focused on the goal of integrating an EBP, in this case MBC, into real world settings (Eccles, et al., 2009) whereas Quality Improvement is a general organizational management approach

to improving care not necessarily focused on EBP integration (Baker, 2006). This proposal reflects a movement in the field (e.g., Dynamic Adaptation Process; Aarons, et al., 2012) to consider planned adaptations of the EBP and systems/organizations to promote EBP integration and sustainment.

C. APPROACH

Overview. Given the underwhelming use of MBC in community mental health settings coupled with the demand for performance outcome assessment (Affordable Care Act), this randomized implementation trial aims to compare the effectiveness of a standardized versus tailored approach to implementation of MBC with co-primary outcomes at the clinician (MBC fidelity) and client (depression severity) levels. We will randomize 12 sites of a large community mental health center (Centerstone) to early or later stage standardized or tailored implementation enrolling 150 clinicians and 500 depressed clients in a pragmatic trial (Thorpe et al., 2009). The main clinician level outcome is MBC fidelity, defined as (a) client completion of the PHQ-9, (b) clinician review of scores in the electronic health record, and (c) discussion of scores in session. Phase 1 (months 0-8) will interface the most widely used and validated depressive symptom severity measure (Patient Health Questionnaire-9 item; PHQ-9; Kroenke, 2001) with the electronic health record; this measure is the main client level outcome. Phase 2 (months 8-38) constitutes the active implementation (5 months) and sustainment (10 months) phase. In both conditions, clients will have the option to complete the PHQ-9 on tablets in the waiting room prior to session, which will feed scores to clinicians via the electronic health record. Sites randomized to the standardized condition will begin with a baseline mixed methods needs assessment (for the purposes of putative mediator data collection) and receive the guideline that MBC is to be used in each session with a depressed client. The standardized condition will include manualized training and triweekly group consultation with experts to promote MBC fidelity and optimize its clinical utility. An implementation team (including a site administrator, opinion leader, MBC champion, and research personnel) will convene prior to each triweekly group consultation to review progress and troubleshoot problems. Sites randomized to the tailored condition will also begin with a needs assessment to identify contextual factors that may serve as barriers to the implementation (guided by the *Framework for Dissemination*; Mendel et al., 2008; see *C7*). Training and triweekly group consultation will be tailored to address these barriers (e.g., clinician attitudes toward MBC). The implementation team (same composition as in standardized) will define a site-specific guideline for MBC use (e.g., monthly) and convene prior to each triweekly group consultation to troubleshoot MBC fidelity barriers. At the start of the active implementation across both conditions, depressed clients of participating clinicians will be enrolled to compare the effect of standardized versus tailored MBC implementation on client outcomes. Phase 3 (months 38-48) will characterize MBC fidelity using electronic health record data capture. The evaluation approach is guided by the *Framework for Dissemination* (Mendel et al., 2008) and includes a baseline needs assessment, implementation/process evaluation (5 months into implementation), and outcome/impact evaluation (15 months into implementation). This design will allow for a direct test of the assumption that voltage drop in treatment outcomes occurs in the context of adapting the intervention to fit the context (Chambers et al., 2014), while simultaneously exploring the effect of standardized and tailored approaches to MBC implementation.

C1. Research Team Expertise, Roles, and Plan for Collaborating

The PI is strategically guided by two tiers of influence with the *first tier* (Kroenke & Ayer) including key leadership to help manage practical aspects of a clinical trial and the *second tier* (Mendel, Simon, Marti, & Rutkowski) including essential content and methodological expertise. Kroenke has notable experience with NIH-funded R01-level effectiveness trials that include depressed patients. Kroenke will mentor PI, Lewis, in the management of a scientific trial. Ayer will provide mentorship in community trials given his experience as site PI for federally funded trials at Centerstone (STAR*D & CATIE); Ayer will oversee participant enrollment and data collection. Lewis will meet with Kroenke and Ayer weekly during the start up phase and twice monthly thereafter. The second tier brings expertise in implementation science and community-based participatory research (Mendel) and measurement-based care and community-based research (Simon); both experts will convene with Lewis at least monthly. Marti and Rutkowski bring quantitative and mixed methods expertise, respectively, with meeting frequency

approximately monthly, but more frequent when expertise is needed (e.g., Rutkowski weekly during active implementation). Quarterly research team meetings will be held with all members.

C2. Centerstone Readiness and Representativeness

As a large behavioral health center with 100+ sites across IN and TN, Centerstone employs approximately 400 clinicians and annually provides services to over 70,000 individuals and families. Centerstone will soon introduce a new electronic health record system through a contract with NetSmart, a leading provider of technology solutions for health and human services, with advanced capabilities through their electronic clinical expert technology (Morrison *Letter of Support*). Given these forthcoming changes and their on-site research institute (Director & Co-I, Ayer), we have an unprecedented opportunity to evaluate an MBC implementation. Centerstone clinicians and clients are highly representative of the broader population; therefore we anticipate that the results of this project will generalize to other community mental health centers. Table 2 depicts demographics for Centerstone clinicians. Consistent with typical community mental health center clinicians in the US, the majority of Centerstone clinicians are Caucasian females with Masters level training. Centerstone clientele represent the broader population of adults seeking mental health services in community settings. Each year, roughly 36,000 Centerstone clients meet criteria for a primary nonpsychotic depressive disorder.

Table 2. Clinician Demographics

Gender: Female	83.4%
Age	43 yrs
Education: Masters	96.0%
Time at Centerstone	6.04 yrs
Licensed: Yes	11%
Weekly Caseload	45
Productivity Requirement	1200 hrs/yr
Met Productivity: yr 11/12	62.0%
Supervisor : Clinician	1:3

C3. Overview of Measurement-Based Care

MBC is the systematic monitoring of client outcomes, using standardized measures, to inform treatment. Recent efforts to implement MBC in community mental health settings have primarily focused on the use of measurement feedback systems and not on the implementation process (e.g., Bickman, 2008). These systems are not readily available due to high costs, nor are they easily integrated within the electronic health record to interface with existing documentation requirements. To address these limitations, our team will introduce the MBC as an evidence-based intervention framework (Scott & Lewis, *in press*) and capitalize on the ways MBC has been used effectively in medicine (Löwe et al., 2004) and in the UK's Improving Access to Psychological Therapies program (Clark et al., 2009). Centerstone clinicians (*N*=165) revealed that fewer than 24% use MBC with depressed clients (Lewis, Scott, Marti, & Ayer, *under review*), which is likely an *overestimate* given the self-report nature of the data (Martino et al., 2009). To improve this rate of MBC use, we will integrate MBC capacities within the electronic health record as well as support and evaluate the implementation process.

C4. PHQ-9 Relevance, Specificity, Sensitivity

We will use the Patient Health Questionnaire depression scale (PHQ-9; Kroenke, 2001) as the primary depression outcome measure in this proposal and as the core component of MBC. The PHQ-9 consists of 9 items that map directly onto the symptoms of a major depressive episode (DSM-IV TR; American Psychiatric Association, 2000), as well as 1 item pertaining to impairment. The PHQ-9 is one of the best-validated depression measures used in >1000 research studies (Kroenke, Spitzer, Williams, & Lowe, 2010). The PHQ-9 has depressive severity cutoff scores, is sensitive to change (Löwe, Kroenke, Herzog, & Gräfe, 2004), and is useful for weekly administration as an indicator of treatment effectiveness (Kroenke & Spitzer, 2002); a five-point change reflects clinically significant reduction in symptom severity (Kroenke & Spitzer, 2002). Three diagnostic meta-analyses and a recent review have confirmed the good sensitivity and specificity of the PHQ-9 in making a major depressive disorder diagnosis (Kroenke, Spitzer, Williams, & Lowe, 2010). Clinicians in our pilot study appreciated the brevity of the measure; clients stated that they thought the PHQ-9 (a) was relevant, (b) would facilitate suicidality endorsement, and (c) would help them to understand their symptoms.

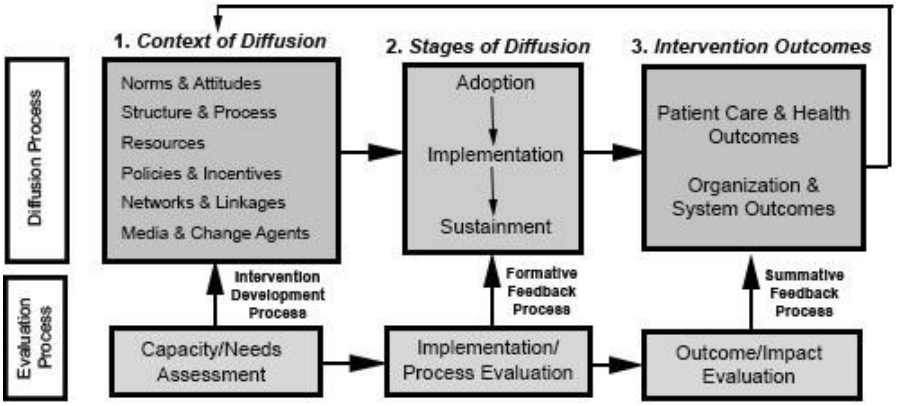
C5. Leveraging Technology: Interfacing Tablet Data Collection with the Electronic Health Record NetSmart (Morrison *Letter of Support*) has agreed to support the integration of the PHQ-9 into the electronic health record system and to work with our team to develop advanced features of the MBC

interface. Total score graphical displays showing session-by-session progress will be available to clinicians within the electronic health record and to clients on their personal health record via the tablet. Clinicians and clients will be able to view individual item-level information, with suicidality highlighted for careful review. Clinically significant change (5-point reduction), and lack thereof, will be flagged from session-to-session. The PHQ-9 will be available to clients on tablet kiosks in the waiting area for completion prior to session. In our pilot, clinicians indicated the importance of tablets as they: (1) felt clinician administration of the PHQ-9 was unnecessarily time-consuming, and (2) wanted to encourage clients to take ownership of symptom monitoring given the potential therapeutic benefits (Eisen, Dickey, & Sederer, 2000). Clients in our focus group unanimously requested private completion of the PHQ-9, indicating that this would promote comfort in sharing suicidality. Tablets are a cost-effective option that has been successfully used in similar protocols (Crits-Christoph et al., 2012). The technological and clinical innovations developed for this proposal present a generalizable protocol (documented in a manual) for widespread implementation given the proliferation of electronic health records. These technological enhancements will be made in both conditions during Phase I (months 0-8; see *C11. Overview of Study Design*).

C6. MBC Fidelity

In this proposal, fidelity to MBC is a three-level categorical variable defined by (a) client completion of the PHQ-9 (No=0, Yes=1), (b) clinician review of scores in the electronic health record (No=0, Yes=1), and (c) discussion of scores in session (No=0, Yes=1). The former two (PHQ-9 completion and clinician review of scores) will be automatically captured through the electronic health record. Clinicians will also check a box in the electronic health record progress note to indicate if they discussed scores in session, as this practice optimizes the effectiveness of MBC (Eisen, Dickey, & Sederer, 2000). Given the known limitations to clinician self-report, this latter fidelity criterion will also be assessed with client self-report via an automated telephone survey immediately after their session. In their first month of implementation, all clinicians (regardless of condition) will be asked to indicate factors they perceived to have limited MBC use. Through a drop-down menu embedded in the electronic health record progress note, clinicians will select contextual factors based on the literature (Dowrick et al., 2009; Garland, Kruse, & Aarons, 2003; Valenstein et al., 2009) and clinician-identified factors (from our pilot data); See Appendix for complete list of options (e.g. lack of time, client refused, clinician forgot).

Figure 1. Framework for Dissemination



C7. The Evaluation Process Figure 1 depicts the *Framework for Dissemination*, which outlines the diffusion and evaluation processes for this study (Mendel, Meredith, Shoenbaum, Sherbourne, & Wells, 2008). Contextual factors (Box 1) theorized to influence the stages of diffusion (Box 2) are identified and both individual and organizational outcomes are considered (Box 3). This framework is based upon the best available research and includes a 3-phase evaluation process (see bottom row) with a community partnership emphasis directly suited to guide this proposal. This model will allow us to evaluate the standardized implementation protocol and to identify contextual factors that may limit or facilitate its effectiveness. This model will also be used to guide the tailored approach to implementation (Mendel; *Letter of Support*).

C8. Complementary Testable Model. Chambers, Glasgow, and Stange (2013) recently put forth the *Dynamic Sustainability Framework* to promote testing of falsifiable hypotheses that program drift from "fidelity" of evidence-based practices leads to a voltage drop in implementation outcomes as compared to effect sizes observed in efficacy trials. Chambers et al. (2013) contend that an alternative hypothesis is important to consider: intentional adaptations to EBP implementation that are informed by community

stakeholders and account for relevant multi-level contextual factors may optimize sustainment and intended outcomes. This proposal intends to test this model. Specifically, the standardized condition requires (via a guideline) that MBC be implemented weekly prior to each psychotherapy session according to its documented efficacy (e.g., Bickman et al., 2008; Whipple et al., 2003). Conversely, the tailored condition will allow the implementation team at each site to adapt this guideline, taking into account their specific context (e.g., monthly MBC implementation).

C9. Pilot Studies

Two Centerstone sites participated in our pilot study to assess the feasibility of the implementation and evaluation process and to inform the implementation protocols for this proposal (*C10. Multifaceted Protocol*).

Baseline Needs Assessment. The mixed methods needs assessment included baseline in-person clinician (*N*=10, 1.5 hours) and client (*N*=6, 1 hour) focus groups and clinician (*N*=24) self-report survey assessments to evaluate the contextual factors of diffusion (Box 1, Figure 1). This needs assessment procedure proved successful for data collection and resulted in 100% clinician participation. At baseline, the Attitudes towards Standardized Assessment scale (ASA, scale ratings 1-5; Jensen-Doss & Hawley, 2010) indicated that clinicians at both sites had generally neutral attitudes about MBC practicality (*M*=3.03, *SD*=0.54 and *M*=3.14, *SD*=0.42, respectively; Cohen's *d=0.*23), its benefit over clinical judgment (*M*=2.88, *SD*=0.46 and *M*=3.40, *SD*=0.93, respectively; Cohen's *d*=0.71), and its psychometric quality (*M*=3.37, *SD*=0.56 and *M*=3.89, *SD*=0.53, respectively; Cohen's *d=0.*95), with Site A demonstrating moderately lower scores across the subscales. Sites also differed on their intention to use MBC; Site B had more positive views of social influence to use MBC (*t*=2.48, *p*=.042) and MBC self-efficacy (*t*=3.49, *p*=.010).

Qualitative analyses of clinician focus groups (2 sites, *N*=10) also revealed site differences in implementation barriers. Notably, significant site differences were observed in the ratio of negative to positive attitudes about MBC (Site A: 44 negative to 17 positive, versus, Site B: 35 negative to 33 positive). Clinicians at Site A frequently cited that MBC was artificial and was overly evaluative of the clinician's abilities*.* At Site B, clinicians endorsed concerns about how MBC would impact clinical productivity, the feasibility of MBC implementation, and the utility of MBC in achieving therapy goals. Simultaneously, clinicians at Site B indicated that MBC would be useful for evaluation and diagnosis and could be used to identify lack of progress*.* Clinic director participants indicated that leveraging technology for client completion would be essential.

Implementation. We then piloted a standardized implementation protocol consisting of (a) embedding the PHQ-9 into the electronic health record (requiring the clinician to verbally assess clients as tablets were not available), (b) a site-specific guideline for PHQ-9 use, and (c) a brief training. The 4-hour training content was based on the work of Persons, Hong, and Koerner (2012); topics included: MBC as a foundational framework; MBC clinical utility; the research evidence for MBC and the PHQ-9; the MBC protocol; research and IT supports to enact the protocol; introduction to the electronic health record interface; and steps for working with lack of progress. These strategies reflect a minimum set of discrete evidence-based implementation strategies that could be blended to facilitate implementation. Pre-training Intention to Use MBC scores were highly correlated with the frequency of subsequent PHQ-9 administration (*r*=.67, *p*=.036). Across sites, 67% MBC penetration was achieved (number of clinicians implementing MBC/number of participating clinicians). Site A achieved 44% penetration while Site B achieved 80% penetration. One limiting factor at Site A was technology problems as the new electronic health record had not yet been introduced and the PHQ-9 did not consistently show up for clinicians. Despite these relatively high penetration scores at the clinician level, this minimal standardized implementation protocol and site-specified MBC guideline resulted in 13.4% (Site A) and 38.6% (Site B) use of the PHQ-9 (by dividing number of administrations by total possible number of administrations) over the course of one year follow up. Unfortunately, we were unable to assess the differential effect of MBC implementation on client outcomes to determine whether adapted guidelines limited MBC's utility. These findings support the proposal in three ways: (a) they emphasize the utility of a

mixed methods needs assessment in identifying *site differences* in barriers, (b) they highlight the importance of tailoring strategies to barriers as this minimal standardized protocol led to superior outcomes in Site B where fewer barriers were present, and, (c) they underscore the potential importance of incorporating technologically advanced solutions for client PHQ-9 completion.

C10. Multifaceted Standardized and Tailored Implementation Conditions

Overview of the Blended Implementation Protocol. Both conditions (standardized and tailored) will employ the same blended protocol of implementation strategies to remove time and resource confounds (see Table 3). The guiding model (*Framework for Dissemination;* Figure 1; Mendel et al., 2008), the best available literature on related efforts to promote MBC implementation (e.g., Evans & Hser, 2004; Harding et al., 2011; Lambert et al., 2005; Morris & Trivedi, 2011; Persons, Hong, & Koerner, 2012; Teruya, Hardy, Hser, & Evans, 2006), personal communication regarding program evaluation of a loosely tailored MBC implementation effort at Group Health clinics (Steinfeld, February 11, 2014), the MBC intervention framework, the partnership goals, and the pilot study defined the blended protocol of implementation strategies (Powell, McMillen, Proctor, et al., 2012). It was determined that embedding the PHQ-9 into the electronic health record was not sufficient but that using tablet computers would be essential to promote feasibility of implementation. The proposed local needs assessment is necessary to assess site-specific contextual factors and to identify opinion leaders and champions. In our pilot, we did not involve clinicians on the implementation team, but literature suggests this may be critical to achieving sustainment (Teruya, Hardy, Hser, & Evans, 2006) and it is consistent with our partnership goals. As such, each site will form an implementation team consisting of the PI, Co-I (Ayer), the site administrator, a clinician identified as an opinion leader (via self-report; Childers, 1986), and a self-nominated MBC champion who will meet for at least 30 minutes prior to each triweekly consultation session. Training and consultation with experts are essential strategies for promoting clinician behavior change and fidelity to the intervention, particularly in the case of evidence-based psychosocial interventions (Herschell et al., 2010). A guideline will be set to specify the frequency of expected PHQ-9 administration with depressed clients. The order of strategies will proceed as follows within each site's 5-month active implementation period: (a) embed PHQ-9 in electronic health record; (b) conduct needs assessment; (c) form implementation team; (d) set guideline; (e) offer initial training; (d) conduct triweekly group consultation meetings (see *C11. Overview of Study Design*). In the 10 months post active implementation, the implementation team will be encouraged to continue to meet and consult with clinicians to promote sustainment. Table 3 depicts the protocol and unique focus of the implementation strategies across conditions. A similar blended protocol of implementation strategies led to successful MBC implementation using the PHQ-9 with 90% completion with over 30,000 clients each quarter at Group Health (personal communication, Steinfeld, February 11, 2014).

Table 3. Standardized versus Tailored Protocol and Focus

Contextual Factor	Strategies	Standardized Focus	Tailored Focus
Resources	PHQ-9 in EHR w/ Tablets	Client Completion on Tablets	Client Completion on Tablets
Networks & Linkages	Form Implementation Team	Monitor MBC Fidelity	To Identify Barriers
Policies and Incentives	Guideline	Each Session w/ Client	Determined by Site
Norms & Attitudes	Training	Standardized Protocol	Targets Barriers
Structure & Process	Progress Note Modifications	For Clinician Score Review	For Clinician Score Review
Media & Change Agents	Consultation with Experts	MBC Fidelity	Targets Barriers

Standardized Condition. The standardized condition includes all aforementioned strategies in the order listed above. The needs assessment will be conducted similar to our pilot study in that it is for data collection purposes only (i.e., no tailoring to identified barriers). The implementation team meetings will focus on monitoring MBC fidelity per the guideline. Depressed clients of clinicians in the standardized condition will be asked to complete the PHQ-9 prior to each session on a tablet in the waiting room

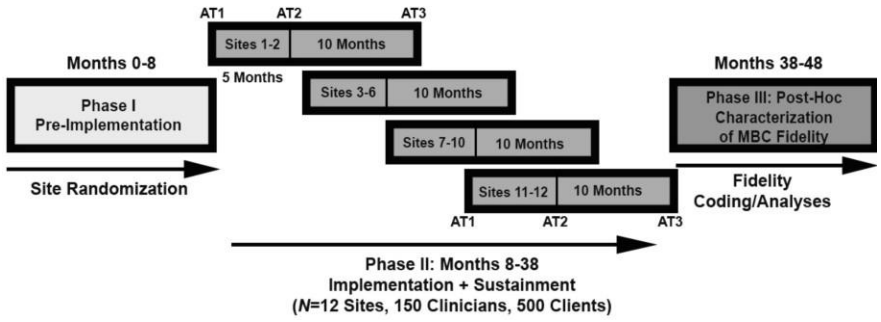
(guideline). PHQ-9 data will then be fed to the electronic health record for clinician review. Training will be offered to all enrolled clinicians using standardized material (described in *C9. Pilot Studies*). Consultation will focus on incorporating clinician review and discussion of PHQ-9 scores in session and providing tips on targeting lack of progress.

Tailored Implementation Condition. Tailored Implementation refers to the *responsive application of implementation strategies and content matched to determinants of practice (i.e., barriers) identified via a needs assessment*. The same strategies outlined in the standardized condition will be employed in the tailored condition, but with content tailored to the site. The needs assessment will reveal contextual factors that may serve as barriers to the implementation process (focus groups will be analyzed using rapid ethnography methods; *C13b. Qualitative and Mixed Methods Data Analysis Plan*). An implementation team will convene to define the site-specific guidelines for PHQ-9 completion. For instance, it may be that Site X decides that monthly PHQ-9 administration is optimal with respect to feasibility and clinical utility. Conversely, Site Y may prefer to have clients complete the PHQ-9 every other session. Depressed clients of clinicians in the tailored condition will complete the PHQ-9 in the waiting room on a tablet computer prior to their appointment with the enrolled clinician based on the site-specific administration guideline. PHQ-9 data will then be fed to the electronic health record for clinician review. Training will be offered to all enrolled clinicians using tailored materials that will target the identified barriers from the needs assessment. For instance, if clinicians at a particular site perceive the PHQ-9 to be irrelevant to clients, training content will incorporate client perspectives on its utility. If clinicians indicate that lack of time is a barrier, then training will incorporate experimentation to streamline review and discussion of scores. The implementation team will focus on identifying remaining barriers for discussion in the triweekly group consultation session. Similar to the standardized condition, consultation will also focus on incorporating clinician review and discussion of PHQ-9 scores in session and providing tips on targeting lack of progress.

C11. Overview of Study Design, Timeline, Sample, and Data Collection

The two years of planning and pilot studies in partnership with Centerstone have informed the implementation protocols as well as its overall research design and data collection procedures. We propose an effectiveness-implementation hybrid design type 2 to allow for simultaneous investigation of clinician- and client-level outcomes. This design will be a dynamic waitlist randomized pragmatic trial comparing the effect of a standardized versus a tailored approach to MBC implementation (Figure 2 & Table 4).

Figure 2. Design Overview



Phase 1: Start-up/Pre-Implementation. Months 0-8 will be characterized by preparatory work for the randomized trial. Little needs to be done to create the research infrastructure in the participating clinics given the existing role of Centerstone Research Institute directed by the proposal Co-I (Ayer). We will prepare the tablet computers for client data collection. We will work with Netsmart (Morrison *Letter of Support*) to link the electronic health record to the PHQ-9 and create the optimal interface for clinicians within the progress note. We will enroll the identified sites (*N*=12), match sites based on size and urban/rural status, and randomize to either *early or later* stage implementation and to condition (standardized or tailored) (Brown et al., 2006). There will be four cohorts each with 5 months of active implementation and 10 months of sustainment monitoring. We will modify the progress note for clinicians to document fidelity (PHQ-9 discussed in session) and reasons for deviation (*C6. MBC Fidelity*). We will pilot the progress note modifications with our advisory board of clinic directors to maximize the information gleaned and to minimize the burden. Because of our use of technology, we will create IT

Frequently Asked Questions and instructions, which will be embedded within Centerstone's internal news. We will also interface study research assistants with clinic staff by attending regular staff meetings at each site. Finally, we will refine measures using established protocols (e.g., Norms; Francis et al., 2004).

Phase 2: Randomized Trial: Implementation & Sustainment. Implementation will take place across 12 sites in months 8-38 using the dynamic waitlist control design (Brown et al., 2006; *C15. Justification and Feasibility*). Specifically, matched sites (based on size and urban/rural status) will be randomized to either *early or later* stage implementation in 4 cohorts (2-4 sites per cohort spaced 5 months apart), with half the sites randomized to the standardized and half to the tailored condition; see Figure 2 for a concise depiction of the implementation timing. The timing of this protocol is based on the published work of Miller et al. (2012) as well as the successful naturalistic MBC implementation at Group Health (personal communication, Steinfeld, February 11, 2014). Beginning at month 8, the earliest cohort (2 sites) will engage in the baseline mixed methods needs assessment (Assessment Time 1; AT1). Using purposeful sampling (Palinkas et al., 2013), a subset of clinicians (*N*=5-8 at each site) representing extreme variation (nominated by clinic directors based on their support for or against MBC implementation) will participate in a 1.5-hour focus group. This sampling approach is critical to gain a wide range of clinician views. Rapid ethnography will then be used to uncover site-specific insights that will guide the content of training and consultation in the tailored condition only (with the aid of mixed method expert Rutkowski; *C13b. Data Analysis Plan*). During the needs assessment, all enrolled clinicians will complete the battery of baseline measures (see Table 5, Section II), from which the opinion leader (Childers, 1998) and self-nominated MBC champion will be identified and invited to join the implementation team. Across conditions, this team will convene triweekly during the 5-month active implementation period to ensure implementation strategy fidelity (Proctor et al., 2013) and review MBC fidelity. Following the needs assessment, clinicians will participate in a 4-hour MBC training workshop (see *C9. Pilot Studies* for content) and will begin triweekly consultation. To characterize the differences in implementation team meetings and consultation between conditions, sessions will be audiorecorded and contextual factors logged by graduate research specialist on the MBC Barriers Log (informed by the *Framework for Dissemination*; Mendel et al., 2008; see *Appendix* for form template). Simultaneously a site team member will log meetings (using the same form) and data triangulated to calibrate site team members and prep for the exit of research personnel. Implementation/Process Evaluations (Mendel et al., 2008; AT2) at the clinician level will occur 5 months after the needs assessment at which point the research personnel will be removed. The site implementation teams will be encouraged to continue meeting to promote MBC sustainment and the responsibility to log and address MBC barriers will transfer completely to the site team members. Outcome/Impact Evaluation (Mendel et al., 2008; AT3) at the clinician and client level will occur 10 months after the Implementation/Process Evaluation. Focus groups will be held with the implementation team at AT3 to review their experience and the site's progress since the research personnel exited the team. All aforementioned steps will be repeated across the remaining three cohorts.

Phase 3: Post Hoc Characterization of MBC Fidelity, Data Analysis, and Manuscript Preparation. Consistent with the Dynamic Sustainability Framework (Chambers, Glasgow, & Stange, 2013), the approach to MBC implementation has the potential to be adapted by sites in the tailored condition. That is, early in the active implementation process (within the first month), the implementation team will generate a guideline for MBC implementation that is specific to their site. Characterizing fidelity for this condition will need to reflect the guideline established for

Table 4. Study Activities

ACTIVITIES	YEAR 1	YEAR 2	YEAR 3	YEAR 4
Study Phase	Phase 1	Phase 2		Phase 3
EHR Modifications				
Clinician Enrollment				
Randomization				
Clinician Assessment				
Active Implementation	Co1	Co2 Co3 Co4		
Sustainment Monitoring		10-months for each cohort		
Client Enrollment & Assessment				
Rapid Ethnography				
Qualitative Coding				
Data Analyses				
Characterize MBC Fidelity				
Manuscript Preparation				

Note. Co = Cohort (2-4 sites with 1-2 randomized to each condition).

each site. For instance, if a site set a guideline to administer the PHQ-9 monthly for each client then actual administration will need to be confirmed monthly. Data capture from the electronic health record will also include whether or not the clinician reviewed the PHQ-9 scores prior to or in session. Finally, with respect to coding of MBC review in session the clinician self-report (via the electronic health record) and client report (via automated phone survey) will be triangulated. Concurrently, focus group data will be formally coded (see *C13b. Qualitative and Mixed Methods Data Analysis*) for manuscript preparation.

C12. Participants: Recruitment, Retention, and Data Collection Procedures

C12a. Clinicians

Recruitment. Participants will be recruited across 12 sites (Clinicians: *N*=187; target: *N*=150) (*Letter of Support;* CEO Guth). The number of sites and clinicians has been determined by a simulation-style power analysis to detect a small effect size predicted by previous research (*C13. Data Analysis Plan*). The main sites have been identified, but not enrolled (*Letters of Support* from regional clinic directors). As there are at least 16 sites from which to select (easily accessible from primary site) and at least 250 eligible clinicians across these sites, we are confident that we can obtain the targeted number of both sites and clinicians. Said differently, even if a site administrator enrolls a site, not all clinicians will need to participate, an important factor to avoid any perception of coercion. Given site diversity, the large number of eligible sites will maximize the likelihood that results will generalize to the broader population of community mental health centers. Sites range in size from 12 to 52 clinicians. Within each enrolled site, clinicians will have the option to participate if they (a) are at least 80% full-time equivalent (b) provide individual psychotherapy to (c) adults with depression (d) in English. These inclusion criteria reflect over 95% of clinicians at the eligible sites. Based on our pilot study, we have experienced that even those who are not supportive of MBC have agreed to participate, therefore making it unlikely that self-selection to participate would limit the generalizability of our sample. During Phase 1 (months 5-8; Table 4), clinician enrollment will begin across all sites and site randomization will occur as site level randomization improves project feasibility and reduces contamination confounds. This decision to randomize by site was also influenced by literature indicating the impact of organizational culture and climate on the implementation process (Aarons et al., 2012; Damschroder et al., 2009), which will be assessed at baseline (AT1).

Data Collection. See *Table 5: Study Measures, Section II* for concise descriptions of the clinician battery. Each contextual factor of diffusion (Mendel et al., 2008) will be assessed via self-report (and qualitatively via focus groups). MBC fidelity is the main clinician level implementation outcome. All clinician measures will be administered across three time points for each cohort with respect to their time since starting implementation: 1) Phase 1: Baseline Needs Assessment (AT1), prior to MBC implementation; 2) Phase 2: Implementation/Process Evaluation (AT2, 5 months in), following the active implementation phase; and, 3) Phase 3: Outcome/Impact Evaluation (AT3, 15 months in) 10 months after the research personnel have exited. Barriers to implementation will be collected for the first month of implementation via the electronic health record.

Table 5. Study Measures

Domain	Measures & Indicators	Interval
I. Client Measures: Effectiveness Outcomes		
Depression Severity	*Patient Health Questionnaire-9* (PHQ-9; Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a 9 item self-report that assesses depression severity and has demonstrated good internal consistency (α=.85-.89) and sensitivity to change (Löwe, Kroenke, Herzog, & Gräfe, 2004).	All Sessions
II. Clinician Measures: Contextual Factors of the Diffusion Process (Putative Predictors, Moderators, & Mediators)		
Demographics	Developed by Lewis & Simons (2011) to assess clinician demographic information and training background.	BL
Norms	A measure of subjective norms will be developed (3 items; Francis et al., 2004) in proposal Phase I and used to assess normative behavior per the theory of planned behavior measurement development manual.	BL, AT2, AT3
Attitudes	*Attitudes Towards Standardized Assessment* (ASA; Jensen-Doss & Hawley, 2010) is a 22-item self-report that assesses attitudes toward use of standardized assessments (e.g., PHQ-9). The ASA has good internal consistency (α=.72-.75) for each subscale (Benefit Over Clinical Judgment, Psychometric Quality, Practicality) and good structural validity.	BL, AT2, AT3
Culture/Climate	*Organizational Culture Scale* (Glaser, Zamanou, & Hacker, 1987) is a 31-item self-report that assesses organizational culture using a 5-point Likert scale for 6 factors: teamwork, morale, information flow, involvement, supervision, and meetings. The OCS has demonstrated strong inter-item reliability (α=.98) among the subscales.	BL, AT2, AT3

Structure/ Process Policies/ Incentives	*Infrastructure Survey* (Keough, Comtois, Lewis, & Landes, 2013) is a 30-item self-report that assesses the impact of infrastructure (e.g., documentation, performance evaluation, productivity requirements) of clinical settings on the implementation and sustainment of empirically supported treatments. Psychometrics will be available Fall 2014.	BL, AT2, AT3
Resources	*Organizational Resources Scale* (ORS; Salanova, Agut, & Peiró, 2005). is an 11-item self report that assesses organizational resources across subscales of Training, Autonomy, and Technology and has good internal consistency (α=.84-.91).	BL, AT2, AT3
Networks & Linkages	We will map the network within each clinic and calculate: the number of links connecting network members (density), and the number of direct connections to and from the opinion leader (centrality).	BL, AT2, AT3
Media & Change Agents	*Opinion Leadership Scale* (OLS; Childers, 1986). The OLS is a 6-item opinion leader self-identification scale that will be employed to identify clinician opinion leaders who may serve as change agents. The OLS has demonstrated good internal consistency (α=.83).	BL, AT2, AT3
III. Clinician Measures: Implementation Outcomes		
MBC Fidelity	**1.** If clients complete the PHQ-9, it will be captured in the EHR (0=No, 1=Yes). **2.** The EHR will reveal whether clinicians reviewed scores (0=No, 1=Yes). **3.** Clinicians will self-report if they discussed scores in session (0=No, 1=Yes). Clients will respond via text to indicate whether clinician initiated score discussion in session. Reasons for MBC fidelity deviation will be captured via clinician report on progress notes.	BL, AT2, AT3
Note	BL(AT1) = Baseline(Assessment Time 1), AT2 = Assessment Time 2, AT3 = Assessment Time 3.	

Retention. The total time required for clinician study participation is 15 months; however, the first two assessments are obtained within the first 5 months. The average length of employment for a clinician at Centerstone is 6 years with an average of 11.72% attrition last year. We anticipate stable clinician participation for the granting period. Fortunately, literature suggests that participatory approaches to organizational change in practice patterns result in lower clinician attrition (Minkler & Salvatore, 2012). Even so, we will recruit 1.25 times more clinicians (*N*=187) to accommodate attrition and achieve the target (*N*=150). Because of the dynamic waitlist design, we will revisit enrollment in Phase 2, 3 months prior to each site's planned implementation. Finally, the design can handle attrition given the within- and between-subjects analyses and multiple assessment points (3 ATs), as can the analyses (multilevel modeling with multiple imputation, described below).

C12b. Depressed Adult Clients

Recruitment. Adult clients (*N*=625; target *N*=500) seeking treatment for depression at Centerstone will be eligible for enrollment in the research study. As this is a pragmatic trial (Thorpe et al., 2009) client participation criteria include: (a) age 18 and above; (b) depression is one of the primary treatment foci based on diagnosis made by clinicians using usual care interview methods to reflect major depressive disorder, dysthymic disorder, depressive disorder NOS, adjustment disorder with depressed mood; (c) significant depressive symptom severity (PHQ-9 total score > 9); (d) receipt of individual psychotherapy; (e) fluency in English; and, (f) new client beginning treatment (g) with an enrolled study clinician during the proposed funding period. Exclusion criterion is minimal: an inability to sign the consent due to lack of competence or inability to read. Intake clinicians will be trained to identify eligible clients and assess if they would be interested in hearing more information about a research study. If the client agrees, the clinician will share the client's contact information with the project coordinator. Because Centerstone has a strong research commitment, clinicians and clients are accustomed to a research environment where the option to participate in studies is more routine than in many community mental health centers. Both Centerstone clinicians and clients have participated in a number of research studies and recruitment is expected to be very straightforward. However, to supplement this approach, Co-I (Ayer, Director of Centerstone Research Institute) will run weekly queries of the Centerstone database (in accordance with Health and Human Services guidance) to identify eligible clients (see *Human Subjects* for previously used HIPAA compliant procedures) who will be contacted by our project coordinator to assess interest in study participation. Once a client has been enrolled, the study team will flag the client in the electronic health record to initiate study procedures for the clinician. Given the number of clients seeking treatment for depression at Centerstone (> 30,000/yr), we anticipate that our client recruitment goal will be feasible.

Data Collection. The goal of client data collection is to determine if routine measurement (in the standardized condition) improves depressive symptom severity and whether adaptations to the MBC assessment schedule (tailored condition) have differential effects on depression outcomes. Clients will complete the PHQ-9 on a tablet kiosk in the waiting room according to site-generated guidelines; this information will be automatically fed into the electronic health record for clinicians to review in session. Given the potential for variable PHQ-9 completion in the tailored condition (based on the site-generated guideline), we will also have clients enrolled in both conditions complete the PHQ-9 at baseline (immediately post consent) and at week 12 of treatment (via automated phone survey). The 12-week window

reflects a commonly used time period in randomized clinical trials during which depressive symptoms are expected to remit. We will also supplement data collection with client 5-axis diagnoses and employment status captured in intake and progress review reports.

Retention. At recruitment, clients will complete a consent form and provide options for multiple contact methods (e.g. multiple phone numbers, address). Centerstone has consistently achieved greater than 75% client retention in federally-funded randomized trials (CATIE, Keefe et al., 2007; STAR*D, Insel, 2006). We will replicate previous efforts to maximize retention in the proposed study. In order to have sufficient power to detect statistical significance and account for client attrition, we intend to recruit 1.25 more client participants (*N*=625) to assure that we achieve our enrollment goal (*N*=500).

C13. Data Analysis Plan: C13a. Quantitative Data Analysis Plan

Data screening. Via frequency distributions and scatterplots, variables will be examined for unusual distributions, out-of-range, and extreme values. We will confirm randomization using chi-square tests, t-tests, and the Kruskal-Wallis nonparametric test. We will test assumptions and underlying statistical models during model fitting. For generalized linear models and multilevel models, we will examine the homogeneity of error, normality of residuals, linearity of relationships between independent and dependent variables, and outliers. For multilevel models, we will assess multivariate normality of random effects.

Missing data. All analyses will adhere to the intention-to-treat approach, which includes all participants assigned to their condition regardless of study completion (Wells, 1999). Multiple imputation (MI), an optimal technique for missing data (Graham, 2009), will include all participants and available data. For all MI analyses, 20 data sets containing plausible values for missing data will be constructed using the Amelia II package for R, which incorporates both cross-sectional and longitudinal information in data imputation (Honaker, King, Blackwell, 2012). Each data set will be analyzed separately and model parameters combined for inferential tests (Rubin, 1987). The missing at random assumption will be assessed using a sensitivity analysis in which a series of pattern-mixture models that adjust parameter estimates for missing data patterns (Hedeker & Gibbons, 1997), will be compared with basic models to identify any potentially non-ignorable missing data patterns.

Aim 1: Hypotheses: *Tailored implementation will outperform standardized in terms of (**H1a**) fidelity.* MBC clinician fidelity was evaluated with two variables: (1) whether the PHQ-9 was recorded in the EHR, and (2) among encounters for which the PHQ-9 was recorded, whether it was discussed. Both outcomes were modeled using generalized linear mixed models with a logit link function for a binary distribution using the lme4 package. All models included random intercepts for clinicians and patients. Models for both outcomes were constructed in an identical sequence. Models comparisons in the model-building sequence described below were evaluated using the Bayesian Information Criterion (BIC); the model with the better BIC was selected for presentation. Several unconditional growth models (i.e., models with only parameters for time) were fit (i.e., linear, quadratic, log-transformed number of months). After establishing the unconditional growth model, additional fixed effects were added in the following sequence: (1) group main effect and (2) group x time interaction. Finally, new versus existing patient status was investigated as a main effect using a dummy variable for new patient status and as a patient status x group interaction.

Aim 2: Hypotheses: *Contextual mediators will be leveraged in the tailored condition, but serve as barriers in the standardized condition.* Mediation models were fit to evaluate which contextual factors (based on clinician-completed surveys, Table 5; and, clinician selection of drop-down menu reasons for MBC deviations captured in the electronic health record) mediate the impact of the implementation condition on both clinician- and client-level outcomes. The two critical effects underlying mediation were evaluated in separate models: treatment condition predicts the mediator (path *a*) and the mediator predicts the outcome (path *b*). Specifically, mediators were assessed at the conclusion of the implementation window and the mediators were used to predict PHQ9 completion in the sustainment window. The *a* path was assessed using linear mixed models with Satterthwaithe degrees of freedom

implemented using the R lmerTest package with a random intercept for clinic. The b path was assessed using generalized linear mixed models with a logit link function for a binary distribution using the lme4 package. ***Aim 3 Hypotheses:*** *Adapted MBC protocols (i.e., tailored condition) will outperform routine weekly administration of PHQ-9s (i.e., standardized condition) with respect to clinically significant change in depression severity from intake to week 12.* Depression severity was analyzed using linear mixed models with Satterthwaithe degrees of freedom implemented using the R lmerTest package. Multiple imputation was used to estimate missing values across 20 datasets in which 22.8% of patients did not complete the 12-week interview. We first assessed whether there was a change in PHQ-9 between intake and week 12 in a mixed model containing patient status as a covariate and random intercepts for patient and clinic. Next, implementation group was added to the model. In addition, number of sessions, number of sessions that the PHQ-9 was recorded, and number of sessions that the PHQ-9 was discussed were added to the model. We also examined the interactions between new patient status and the focal variables. ***Power calculations***. A power analysis for the multilevel models for Aim 1 was assessed with Monte Carlo studies in which power is the proportion of significant effects (2-tailed α, $p < .05$) for parameters of interest observed over repeated analyses of simulated data (Muthén & Muthén, 2002; Thoemmes, Reiser, & MacKinnon, 2010) using MPlus (version 7). For each model, 10,000 data sets were simulated and analyzed. Data in the Monte Carlo studies were simulated with the goal of identifying the smallest detectable effect size with power > 80. Dropout was simulated to reflect an increase of 5% missing data per wave. Repeated measurements were nested within participants (ICC = .50) and participants were nested in sites (ICC = .05). Average effect sizes for Aim 1 analyses were computed using an approximation of Cohen's *d* for growth models (Feingold, 2009). Using this metric, we are sufficiently powered to detect effect sizes as small as $d = .46$ for the clinician models ($N = 150$) and effect sizes as small as $d = .30$ for the client models ($N = 500$). For Aim 2, we conducted power analyses for the hypothesized mediation effects with the same assumptions described above but with the use of effective samples size estimates (an ICC corrected sample size) based on a design effect adjustment (Bickel, 2007) in order to use standard effect size metrics. The κ^2 effect size for mediation (.01, .09, and .25 represent small, medium, and large κ^2 respectively) was computed (Preacher & Kelly, 2011). We are sufficiently powered to detect effect sizes as small as $\kappa^2 = .16$ for the clinician models and effect sizes as small as $\kappa^2 = .10$ for the client models. For Aim 3 analyses, we are sufficiently powered to detect effect sizes as small as $r = .27$ for clinicians and as small as $r = .21$ for clients. The planned sample sizes are consistently sufficient for detecting medium effect sizes for clinician outcomes and small effect sizes for client outcomes, with the power to treat site as a random effect based 6 sites per condition (Atkins & Baldwin, 2013).

C13b. Qualitative and Mixed Method Data Analysis Plan

Overview. Mixed methods will be used to integrate findings from Aim 2 using a quantitative + qualitative structure (wherein both types of data are collected simultaneously) to achieve the function of data expansion for the purposes of evaluation and elaboration (Palinkas et al., 2011). We will use a connecting process (whereby the datasets build upon one another) and work closely with our mixed methods expert (Rutkowski). Rapid ethnography (Millen, 2000) will be used to synthesize the needs assessment data only in the tailored condition to characterize participant experiences. Focus groups will be analyzed separately to characterize participant responses within each site, across conditions. Graduate student researcher (Scott), who was trained in qualitative inquiry methods during the pilot studies, will work with the postdoctoral fellow to train research assistants to identify and code analyzable units of meaning in the focus group transcripts. An iterative approach to coding will resolve disagreements through research team discussion. Inductive analyses based on emergent themes rooted in grounded theory will be conducted (using QSR N-Vivo software). Codes will also be assigned based on contextual factors using Mendel et al.'s (2008) *Framework of Dissemination*. The final list of consensus codes will include themes established *a priori* and through emergent themes analysis.

Using the U.S. NIH guidelines for mixed methods best practices (Creswell, et al., 2011), we will connect the quantitative and qualitative datasets in QSR N-Vivo to allow for case-specific pattern identification and hypothesis testing. For example, we will enter clinician-specific MBC fidelity data

(categorized as “none”, “low”, “moderate”, “high”) and query each qualitative theme for matched clinician focus group quotes in order to investigate the influence of contextual factors on level of MBC fidelity. Based on pilot study qualitative findings, we anticipate that focus groups will yield both positive and negative valenced statements for each of the a priori and emergent themes. We will investigate the extent to which differences exist in the valence of contextual themes between conditions. This approach will allow us to distinguish factors that might explain the differences in the quantitative findings, and notably MBC fidelity.

C14. Potential Problems & Alternative Strategies.

Our hypothesis is that tailored implementation will outperform the standardized approach. However, it is possible that this hypothesis will not be supported. Findings of this nature would not be undesirable, but rather would illustrate that while emerging research suggests the need to contextualize implementation interventions (Fixsen, 2005; Wallerstein & Duran, 2010), this customization compromises ultimate outcomes—a critical realization for the field of implementation science. Furthermore, if we are unable to detect mediators of implementation and effectiveness outcomes included in this proposal, it may suggest the need to re-evaluate the *Framework of Dissemination*. Specifically, putative mediators of the dissemination and implementation process not included in this model might require empirical investigation. Our qualitative analyses will allow for careful examination of unanticipated mediators. At the level of the clinician, we anticipate substantial variability in competency and general approach to psychotherapy. However, we are not concerned about the effects of this variability on study outcomes because (1) randomization should result in equivalent variability across conditions and (2) MBC is conceptualized as transtheoretically relevant, regardless of the therapist’s orientation or training.

C15. Justification & Feasibility.

We selected an effectiveness-implementation hybrid to investigate one co-primary aim that focuses on (1) implementation outcomes at the clinician level and (2) effectiveness with respect to client outcomes. To test the Dynamic Sustainability Framework (Chambers et al., 2013), we will need to compare the clinical effectiveness of the adapted use of MBC (tailored) as compared to the empirically supported MBC approach (standardized). Simultaneously, because no studies have attempted to scale up MBC in community mental health, we need to evaluate the implementation (clinician-level: fidelity) outcomes. The effectiveness-implementation hybrid design type 2 was identified as the optimal and innovative design solution for this proposal.

Within the effectiveness-implementation hybrid design, we will randomize sites to condition using a dynamic waitlist controlled approach. Half of the sites will receive a standardized approach to implementation and the other half will receive a tailored approach. This design reduces the effect of management- or clinician-level readiness or client factors that might otherwise confound the training effects allowing for unbiased data (Brown, et al., 2006). This design also affords the opportunity to conduct blocking on smaller time units and statistically provides large gains in efficiency (range from 33 to 100% gains). Moreover, training efficiency is achieved as not all sites must be trained at once, therefore allowing the same trainer(s) to train all sites to reduce any possible effect at the level of trainer expertise (Herschell, Kolko, Baumann, & Davis, 2010).

We have already piloted many of the implementation strategies and the evaluation approach (*C8: Pilot Studies*). Moreover, Centerstone has successfully completed >150 studies since 2003; two of these studies were NIMH-sponsored (CATIE, Keefe et al., 2007; STAR*D, Insel, 2006), whereas others involved wide-scale implementation of EBPs for SAMHSA-sponsored program evaluations. Co-I (Ayer) has coordinated many of these multi-site clinical trials at Centerstone. This proposal’s design considerations and the established strong collaborative relationship of our investigative team, we have no concerns regarding this proposal’s feasibility.

C 16. Implications and Future Directions

Few experimental implementation studies have been conducted. Findings from this proposal have the potential to: (1) yield a robust theoretical and practical model delineating contextual factors and

evaluative processes for implementation in an academic-community partnership; (2) demarcate the benefit of using standardized versus tailored protocols for implementation; (3) establish a blended protocol for MBC implementation with capacity for generalization to community mental health centers nationwide; and, (4) highlight contextual factors responsible for sustained MBC implementation. With depression maintaining its place among the nation's top chronic illnesses, costing billions of dollars annually, positive findings from this proposal will present a feasible and effective approach to alleviating great societal burden through a minimal intervention needed for change. This study will lay the groundwork for subsequent research (by establishing progress monitoring) to enhance usual care for multiproblem clinical presentations, should MBC effects plateau and additional interventions be necessary.

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SUMMARY SAFEGUARD STATEMENT

IRB STUDY NUMBER: 1407578183
PRINCIPAL INVESTIGATOR: Cara C. Lewis, PhD
DOCUMENT DATE: 7/7/16

STUDY TITLE: **Standardized versus Tailored Implementation of Measurement Based Care for Depression**

SECTION I: STUDY DESCRIPTION

A. Please describe (in lay terms) the general objective(s) of the proposed research, including research question(s), hypothesis, and a short summary of the main interactions/interventions. If appropriate, describe any usual methods, that were considered, but not chosen, and why.

Depression remains among the nation's top 10 chronic illnesses, costing over $80 billion annually. Depression has been called the "Common Cold" of mental illness, but one with serious risk of morbidity and mortality. There are now many evidence-based practices for the treatment of depression, but unfortunately these practices remain largely unavailable to clients receiving services in community mental health centers. Measurement Based Care (MBC) is a relatively simple evidence-based intervention framework. MBC, by definition, is the practice of using symptom measurement to inform mental health care. Physicians who routinely measure the patient's blood pressure when the treatment target is high blood pressure demonstrate the medical corollary of MBC. When MBC is used in the treatment of depressed adults, it has been shown to improve outcomes by identifying clients who are not making progress and reducing the likelihood that clients will deteriorate in treatment. However, despite the demonstrated effectiveness of MBC, the majority of community mental health counselors (i.e., clinicians) do not regularly assess target problem symptoms to guide their work over the course of treatment. To our knowledge, no studies to date have focused on the process of implementing MBC in community mental health settings. The long-term goal of this research project is to provide generalizable and practical recommendations about implementation approaches that promote MBC use and fidelity in community mental health centers. Specifically, this study will test a standardized versus a tailored approach to implementing MBC in one of the nation's largest not-for-profit providers of behavioral health services. Although touted as superior, tailored implementations have rarely been compared to standardized approaches. Moreover, recent research has demonstrated an apparent need to adapt evidence-based practices to fit the specific context in which they are being implemented, particularly if they are to be sustained. This proposal reflects a movement in the field of implementation science in which planned adaptations are being tested and compared to standardized versions. The proposed research is a three-phase, mixed methods (quantitative/qualitative) study to investigate the effect of these two different approaches to MBC implementation on both clinician-level (e.g., MBC fidelity) and client-level (depression symptom change) outcomes. We will focus on contextual factors (e.g., attitudes, resources, process, etc.) that may influence the implementation process with the goal of identifying a generalizable and practical way of bringing MBC to community mental health centers treating depressed adults.

SECTION V: SUBJECT POPULATION

A. **Subject Population**. Check all subject population categories below for which there is a reasonable expectation of enrollment into this research study:

- ☐ **Children** (Complete the Request Form for the Inclusion of Children in Research)
- ☐ **Cognitively Impaired** (Complete the Request Form for the Inclusion of Cognitively Impaired Individuals in Research)
- ☒ **Economically/Educationally Disadvantaged**
- ☐ **Pregnant Women, Human Fetuses, or Fetal Material** (Complete the Request Form for the Inclusion of Pregnant Women, Human Fetuses, and Neonates in Research)
- ☐ **Prisoners** (Complete the Request Form for the Inclusion of Prisoners in Research)
- ☐ **Subjects Outside of U.S. Targeted for Enrollment** (Complete the Transnational Research Information Form)
- ☐ **Veterans** or research funded by the VA, utilizing VA effort, property or resources, or enrolling VA patients. (Complete the Request Form for VA Research)
- ☐ **Students**. When there is a teacher-student relationship dynamic, complete the following questions:

B. **Inclusion/Exclusion**.

Clinicians

Inclusion Criteria. Clinicians will be eligible for the study if they: 1) provide individual psychotherapy; 2) provide psychotherapy to adults with depression (based on their self-reported typical and current caseload (i.e., clinicians will learn in the eligibility

discussion that if they consent to participate in the study then they must have eligible clients to potentially enroll as well); 3) conduct psychotherapy sessions in English.
Exclusion Criteria. Clinicians will be excluded if they indicate during enrollment that they intend to leave the organization and will be unable to complete all study phases.

Clients
Inclusion Criteria. As this is a pragmatic trial (Thorpe et al., 2009), clients will be eligible for the study if they: 1) are age 18 and above; 2) have depression as one of the primary treatment foci: diagnosis will be made by clinicians using usual care interview methods and can include any of depressive disorder diagnosis (e.g., major depressive episode, dysthymic disorder); 3) have significant depressive symptom severity (PHQ-9 total score > 9 at intake); 4) will receive individual psychotherapy; 5) are receiving psychotherapy treatment with an enrolled clinician during the proposed funding period.
Exclusion Criteria. Because of the pragmatic nature of this trial, there is only one exclusion criterion for clients. Specifically, clients will be excluded if they are unable to provide verbal consent due to severe mental illness or inability to read, for instance.

Administrators
Inclusion Criteria: Administrators must have some sort of administrative role at the site or as part of Centerstone as a whole. However, the position they must have an administrative role within one of the twelve sites that will be participating in project.
Exclusion Criteria: The only exclusion criteria are that 1) the administrator must be involved with one of the twelve sites participating in the project. Those who have an administrative role in one of Centerstone's other sites will not be eligible to participate. 2) Those who indicate they intend to leave the organization and will be unable to complete all study phases will not be eligible.

Office Professionals
Inclusion Criteria: Office professionals must have a role at one of the twelve participating Centerstone sites.
Exclusion Criteria: The only exclusion criteria are that 1) the office professional must be involved with one of the twelve sites participating in the project and 2) those who indicate they intend to leave the organization will be unable to complete all study phases will not be eligible.

Staff
Inclusion Criteria: Staff must provide services to the client at one of the 12 participating Centerstone sites or provide support to another staff member providing services to the client. Depending on the site, staff could include but is not limited to nurses, doctors, psychiatrists, and case managers.
Exclusion Criteria: The only exclusion criteria are that 1) the staff must be involved with one of the twelve sites participating in the project and 2) those who indicate they intend to leave the organization will be unable to complete all study phases will not be eligible.

C. **Number of Subjects**.

Clinicians
Clinicians will be recruited from 12 Centerstone sites across two states (Indiana and Tennessee). Approximately 187 clinicians (average of 16 per site) will be recruited during the latter half of Phase 1 of the study (months 5 to 8) to achieve our target enrollment of 150 (accounting for clinician turnover) and allow for initial site randomization (to early or late and standardized or tailored implementation) to occur just prior to Phase 2 (months 8-38).

Clients
Clients seeking treatment for depression at the 12 enrolled Centerstone sites will be recruited for participation in the proposed research during Phase 2 of the study (months 8 to 38; we will stop recruitment at month 35 to allow for the necessary 12 week assessment to be completed during Phase 2). Approximately 625 clients will be recruited (given the potential for unplanned attrition) to achieve our goal enrollment of 500 clients (an average of 42 per site, 3 per clinician) based on power analyses.

Administrators
Administrators will be recruited from the 12 enrolled Centerstone sties across two states as well as those who have a larger role within Centerstone, such as the executive director. About 12 administrators (about 1 per site) will be recruited during the latter half of Phase I of the study (months 5 to 8) to participate in individual interviews and then later implementation team meetings.

Office Professionals
Office professionals will be recruited from the 12 enrolled Centerstone sites across two states. Approximately 12 office professionals (about 1 per site) will participate in the implementation team meetings.

Staff
Staff will be recruited from the 12 enrolled Centerstone sites across two states. Approximately 300 staff members will participate by completing small batteries of questionnaires.

SECTION VII: STUDY PROCEDURES

The study consists of three main phases each is described briefly below.

Phase 1: Start up/Pre-Implementation (months 0-8) will interface the most widely used and validated depressive symptom severity measure (Patient Health Questionnaire-9 item; PHQ-9; Kroenke, 2001) with the electronic health record. Enrollment of clinician, administrators, office professionals, and client participants will begin. Randomization at the site level will occur to one of the two conditions, standardized or tailored implementation of measurement-based care for depression. In addition, sites will be randomized to early and late stage implementation across 4 cohorts (2-4 sites in each cohort), with each cohort having 5 months of active implementation and 10 months of sustainment monitoring.

Phase 2: Randomized Trial: Implementation & Sustainment (months 8-38) constitutes the active implementation (5 months) of measurement based care and sustainment (10 months) phase. Clinician, administrator, office professional, staff, and client participation will occur during this phase.

Finally, phase 3: Post Hoc Characterization of MBC Fidelity, Analysis and Manuscript Preparation (38-48 months) will consist of post-hoc characterization of measurement-based care fidelity (MBC fidelity; Appendix B.2), defined as (a) client completion of the PHQ-9, (b) clinician review of scores in the electronic health record, and (c) discussion of scores in session.

Clinicians: Across Both Conditions (i.e., Standardized and Tailored)

Phase 1 (Months 0-8)

Pre-Implementation. The research team will recruit clinicians for participation via email and site visits. The study research assistants assigned to the Centerstone sites will follow-up with interested clinicians over the phone to provide additional information or answer any questions s/he may have about participating in the study.

Phase 2 (Months 8 – 38)

5-Month Active Implementation. Beginning at month eight, clinicians who provide individual psychotherapy to adults with depression (based on their self-reported typical and current caseload (i.e., clinicians will learn in the eligibility discussion that if they consent to participate in the study then they must have eligible clients to potentially enroll as well) and who conduct psychotherapy sessions in English will engage in the baseline mixed methods needs assessment. This assessment will consist of a battery of surveys and then, following the completion of these surveys a focus group will take place. Clinicians will be asked to complete the following baseline battery of self-reports (Appendix A): Demographic Questionnaire (Lewis & Simons, 2011; Appendix A.1); Progress Monitoring Theory of Planned Behavior (Francis et al., 2004; Appendix A.2); Attitudes toward Standardized Assessment-Monitoring and Feedback (Jensen-Doss et al., *in press*; Appendix A.3); Monitoring and Feedback Attitudes Scale (Jensen-Doss et al., *in press*; Appendix A.4); Monitoring As Usual Measure (Lyon et al., 2015; A.5); Evidenced-Based Practices Attitudes Scale (Aarons, 2004; A.6); Survey of Organizational Functioning (Broome et al., 2007; A.7), Implementation Climate (Jacobs et al., 2014; A.8); Implementation Climate Scale (Earhart et al., 2014; A.9); Barriers and Facilitators to Implementing Survey (Salyers, Rollins, McGuire, & Gearhart, 2008; A.10); Sociometric Questionnaire (Valente et al., 2007; A.11); Opinion Leadership Scale (Childers, 1986) and self-nomination question (A.12); Implementation Leadership Scale (Aarons et al., 2014; A.13); and Perceptions of Adopting Measurement-Based Care (Moore & Benbasat, 1991; A.14). All questionnaires will be completed online using assessment software by emailing them a link or via hard copy (in-person). These questionnaires will take about 60 minutes to complete and clinicians who complete the baseline assessment will receive $50 compensation. Using the data from these surveys, a subsample of clinicians at each site, selected using purposeful sampling for extreme variation (Palinkas et al., 2013), will be asked to participate in a 1.5 hour focus group (Appendix E.1). Clinicians who participate in the focus group(s) will receive $25 compensation. Focus groups will be recorded and transcribed with data de-identified for the purposes of qualitative coding. Staff who do not provide individual psychotherapy to adults with depression in English (for example, this could be clinicians who primarily provide therapy to children, groups, diagnoses other than depression and/or conduct therapy in another language; or psychiatrists, nurses, nurse practitioners, case managers, other non-clinical staff) will engage in an abbreviated version of the battery of self-report measures which will include: (Appendix A): Demographic Questionnaire (Lewis & Simons, 2011; Appendix A.1); Progress Monitoring Theory of Planned Behavior (Francis et al., 2004; Appendix A.2); Attitudes toward Standardized Assessment-Monitoring and Feedback (Jensen-Doss et al., in press; Appendix A.3); Monitoring and Feedback Attitudes Scale (Jensen-Doss et al., in press; Appendix A.4); Evidenced-Based Practices Attitudes Scale (Aarons, 2004; A.6); Sociometric Questionnaire (Valente et al., 2007; A.11); Opinion Leadership Scale (Childers, 1986). All questionnaires will be completed online using assessment software by emailing them a link or via hard copy (in-person). The questionnaires will take less than 30 minutes to complete and staff who complete the abbreviated baseline assessment will receive $20 in compensation per assessment point. Note, from this point forward we will refer to this group of staff as the "general staff" to differentiate them from those completing the full baseline battery which we will refer to as simply "clinicians."

Following the needs assessment, clinicians will be asked to participate in one four-hour training session that will introduce either the standardized MBC approach or the tailored MBC procedures. Clinicians will receive Continuing Education Units (i.e., education credit needed for licensure; maximum of four; to be determined) for attending the training. One training will be held at each site. The training will be scheduled such that all participating clinicians can attend and clinicians will receive productivity coverage credit for the four-hour training. In addition, immediately following the training a small battery of questionnaires will be administered to the clinicians to understand their training experience. This battery includes: Acceptability, Feasibility, Appropriateness for Training (Lyon, 2011, A.16-3); Post-Training Workshop EVALuation (TCU Institute of Behavioral Research, 2009; A.17); Clinical Teaching

Assessment Instrument (Litzelman, Stratogs, Marriot, & Skeff, 1998; A.18); Counselor Rating Form-Short (Corrigan & Schmidt, 1983; A.15), Progress Monitoring Theory of Planned Behavior (Francis et al., 2004; Appendix A.2); Attitudes toward Standardized Assessment-Monitoring and Feedback (Jensen-Doss et al., *in press*; Appendix A.3); Monitoring and Feedback Attitudes Scale (Jensen-Doss et al., *in press*; Appendix A.4); Perceptions of Adopting Measurement-Based Care (Moore & Benbasat, 1991; A.14) and Measure of Effective Attributes of Trainers (Boyd et al, unpublished; A.22). This will be completed by clinicians in-person following the training and will take about 20-25 minutes to complete. Clinicians will receive $10 in compensation for completing the post-training battery.

In addition, one opinion leader and one self-nominated MBC champion (the opinion leader could also be the MBC champion, but in some cases this will be two different people) will be invited to participate on the implementation team based on the survey results from the needs assessment. The implementation team consists of research team members, site administrator, and 2-4 clinician opinion leader and champion, a client, and office professional. This team will convene for triweekly meetings during the 5-month active implementation phase and they are encouraged to meet without the researchers present during the 10-month follow-up period to facilitate identification of additional barriers (the number of actual meetings and attendance will be documented). Clinicians will be informed that consultation and training sessions will be audio-recorded for research team coding purposes, with the focus on capturing the barriers that emerged and the function of the discussions. Clinicians will be reminded at the beginning of each session not to use client names during consultation sessions to protect client confidentiality. Audio-recorded sessions will be transcribed using the procedures outlined for the focus groups. No clinician study participant identifying information will be retained in the transcripts and only 6-digit anonymous identification numbers will be used. The form found in Appendix B (MBC Barriers Coding Form; Appendix B.1) will be completed by implementation teams during their triweekly meetings; deidentified MBC Barriers Coding Forms will be analyzed for the purposes of research. Additionally, clinicians will have the option to complete the form found in Appendix B (MBC Consultation Form) prior to the triweekly meetings to facilitate consultation, the deidentified MBC Consultation Form form will also be analyzed for the purposes of research. Finally, a battery of surveys will be administered in-person and completed by those on the implementation teams at 5-months and 15-months during an implementation team meeting. These surveys include the Acceptability, Feasibility, Appropriateness for Implementation Teams and Conditions (Lyon, 2011; Appendix A.16-1, A.16-2); Mendel Implementation Team Survey (A.19), and Edmondson Team Measure (Edmondson et al, 1999; A.20). These surveys will take about 25 minutes to complete and staff will receive $15 in compensation per assessment point.

Clinicians have the option of entering and reviewing the PHQ-9 data with clients in the EHR. When they enter the data they should be given the option of answering additional questions about if/why they reviewed scores with client (see Appendix B.2). Due to technological issues with the EHR, not all clinicians currently have the option of completing these questions. To ameliorate this issue, clinicians at affected sites will have the option of filling out this information on paper each week (see Appendix B.4-1, B.4-2). This data will then be collected in person by CRI staff who will transfer if to a secure database. To offset the inconvenience of filling out a paper version of the questions and to encourage clinicians to do so, $1 will be included with each paper survey.

At the end of the 5-month active implementation, clinicians will be asked to complete the same questionnaires in the above-listed baseline battery. Similar to the baseline battery of self-reports, these assessments will be completed online or via hard copy, and clinicians will receive $50 per assessment battery completed. In addition, a subsample of clinicians at each site similar to at the beginning of Phase 2 will be asked to participate in a 1.5 hour focus group (Appendix E.1). Clinicians who participate in the focus group(s) will receive $25 compensation. A subsample of clinicians at each site will also be invited to participate in individual exit interviews regarding their views about and use of the PHQ-9 (Appendix A.21). Clinicians who participate will receive $20 compensation.

10-month Post-Implementation/Sustainment. Towards the end of the post-implementation/sustainment phase, another focus group with a subsample of clinicians from each site selected via purposeful sampling will occur (Appendix E.1). Similar to the focus group at the beginning of Phase 2 and end of Phase 2, participants will be compensated $25. The same aforementioned baseline and 5-month active implementation assessment battery will be re-administered towards the end of the 10-month post-implementation/sustainment phase to assess factors influencing sustainment of MBC. Similar to the assessments before, clinicians will receive $50 for completing the assessment.

The job category/title, licensure, supervisor information and demographics will also be obtained from the electronic health records at each site to obtain information about clinician experience. This information will be retrieved by a trained Centerstone Research employee who will be de-identify the information before providing it to the research team.

Clients: Across Both Conditions (i.e., Standardized and Tailored)

Phase 1 (Months 0-8)

Pre-Implementation. A research assistant will contact potentially eligible clients via telephone and will perform an initial 10-20 minute phone screen to assess eligibility (RCR.3). A telephone version of the Patient Health Questionnaire-9 (PHQ-9; Appendix C.2) will be performed during the phone screening with the Centerstone Research Institute research assistant (CRI RA) in both conditions. This questionnaire should only take about five minutes to complete and clients will receive a $5 incentive for completing the PHQ-9 regardless of their study eligibility. The client is deemed eligible if the client indicates that depression is a primary focus of treatment, s/he is seeking treatment with an enrolled study clinician, and s/he scores a 9 or higher on the PHQ-9. If the client is eligible, s/he will be asked to respond to a Client Demographics Questionnaire (Appendix C.1) over the phone during this initial screen. The data obtained from the initial PHQ-9 screen (RCR.3) and demographics questions is to be collected, labeled with a 9-digit anonymous research ID, and kept in a secure database in the secure server at Centerstone. If s/he is eligible and interested in participating, s/he will be asked to give verbal consent to participation over the phone during the initial screen conducted by the CRI RA. The CRI RA will also offer to call the client back if s/he would like time to review the informed consent statement before agreeing to participate. After a client verbally consents to participation or indicates that they would like time to review the consent statement, a

Welcome Packet, which will, contain the informed consent, authorization for the release of health information for research, and a stamped and return-addressed envelope will be sent to the client's address. The client will a $5 gift card as compensation for PHQ-9 completion in the initial phone screen. If the client signs and returns the release of health information either via the pre-paid envelope or in person at their next session (additional information on the informed consent process can be found below in Section XII: Informed Consent Process), s/he is enrolled in the study. At this point the client will receive an additional $5 compensation. If the client consents to research participation and the authorization for the release of health information for research, their verbal PHQ-9 and demographics data from the initial phone screen will be utilized as a baseline measure and be transported to IU for storage, given that the consent includes that the PHQ-9 completed for the eligibility screener and demographics questions can be used for the purposes of research. The 5-Axis diagnosis and employment, status, program activity involvement (i.e., type, start date, end date, care coordinator involved, face-to-face contact, location, reasons for discharge), date of first and last service, date of intake session, admission status (active/inactive), body mass index (BMI), age at BMI, demographics, medication use (i.e. prescription type, dosage, units, number of pills), and blood pressure (Appendix C.3) will also be retrieved from the clinician's intake report and health records to obtain information about comorbidities and functioning for all enrolled clients. This information will be retrieved by a trained Centerstone Research employee who will de-identify the information and then provide it to the research team.

Phase 2 (Months 8-38)

Client's Treatment (weeks 0-11). Clients in the standardized condition will be asked to complete the hard copy PHQ-9 forms in the waiting room prior to every session with their enrolled study clinician, while clients in the tailored condition will complete the PHQ-9 according to the measurement-based care guidelines defined by the implementation team at each site. In all cases, clients will fill out the hard copy PHQ-9 prior to a session located in waiting room kiosks and completing the survey should only take about five to ten minutes. The client will then hand the completed PHQ-9 to his or her clinicians who will then enter it into the electronic health record so that the clinicians can review the PHQ-9 scores with the clients during the session. The CRI RA will pull the PHQ-9 data for all enrolled clients across the course of their treatment and provide it to the research team using the 9-digit anonymous identification number. In addition to the PHQ-9, clients will be asked to respond to a telephone or text message-based survey after each psychotherapy session to inquire as to whether their clinician discussed PHQ-9 scores in the session immediately preceding (Yes/No/NA) (Appendix C.4). Client can earn $2 for every survey they complete for up to $20. So clients may be able to earn an additional $20 for completing these surveys after each session and the amount attained will be mailed with the $10 incentive for completing the week 12 PHQ-9 (described below).

Client's Treatment (week 12). Clients will be reassessed for depression symptom severity via a phone interview (like the initial screen) at week 12 of their treatment, regardless of number of treatment sessions attended (Appendix C.2). A postcard reminder may be sent to clients before the phone interview as a reminder. The project coordinator and CRI RAs will track client time since entering treatment, beginning with the intake assessment. Clients will be mailed $20 as an incentive for completing the week 12 assessment.

Client's Treatment (week 13 and beyond). Upon completion of the telephone assessment at week 12, PHQ-9 data collection for all enrolled clients will continue to occur according to the site guidelines for the duration of the study funding-period.

Note. In the unlikely case that an enrolled Centerstone client does not own a telephone, the research assistant will meet the client on-site for a hard copy version of the PHQ-9 in instances where a telephone version is supposed to administered (e.g., for determining initial eligibility and in week 12). In addition, if a client does not have unlimited text messaging, we will offset the costs for the text message surveys by providing the client with $5.

We will be asking permission to audiorecord client's therapy sessions for research purposes. These tapes would be reviewed and coded by an objective team of researchers trained in confidentiality to understand how measurement-based care is used in the community and to improve our understanding of how to help clients using measurement-based care. Only a subsample of client's audiotaped sessions would be reviewed and coded and these tapes will be randomly selected.

<u>Administrators: Across Both Conditions (i.e., Standardized and Tailored)</u>

Phase 2 (Months 8 – 38)

5-Month Active Implementation. Administrator from each site will be asked to participate in a 30 minute individual interview either in-person or phone-based at the beginning of Phase 2 (Appendix E.2 and E.3). Administrators who participate in the individual interview will receive $20 compensation. Individual interviews will be recorded and transcribed using VoiceBase technologies with data de-identified for the purposes of qualitative coding.

In addition, one administrator per site will be invited to participate on the implementation team at each site. The implementation team consists of research team members, site administrator, 2-4 clinician opinion leader and champion, a client, and office professional. This team will convene for triweekly meetings during the 5-month active implementation phase and they are encouraged to meet without the researchers present during the 10-month follow-up period to facilitate identification of additional barriers (the number of actual meetings and attendance will be documented). Administrators will be informed that the meetings will be audio-recorded for research team coding purposes, with the focus on capturing the barriers that emerged and the function of the discussions. Administrators will be reminded at the beginning of each session not to use client names during consultation sessions to protect client confidentiality. Audio-recorded sessions will be transcribed using the procedures outlined for the focus groups. No administrator study participant identifying information will be retained in the transcripts and only 6-digit anonymous identification numbers will be used. The form found in Appendix B (MBC Barriers Coding Form; Appendix B.1) will be completed by implementation teams during their

triweekly meetings; deidentified MBC Barriers Coding Forms will be analyzed for the purposes of research. Additionally administrators will complete the battery of self-report measures (the same one that clinicians complete) and receive $50 compensation at the baseline, 5-month follow up, and 10-months after the active implementation period. Finally, a battery of surveys will be administered in-person and completed by those on the implementation teams at 5-months and 15-months during an implementation team meeting. These surveys include the Acceptability, Feasibility, Appropriateness for Implementation Teams and Conditions (Lyon, 2011; Appendix A.16-1, A.16-2); Mendel Implementation Team Survey (A.19), and Edmondson Team Measure (Edmondson et al, 1999; A.20). These surveys will take about 25 minutes to complete and staff on the implementation team will receive $15 in compensation per assessment point.

At the end of the active implementation period, the administrator will be invited to participate in the Contamination interview. This interview will be conducted in person or on the phone and will take about 30 minutes to complete.

Office Professionals: Across Both Conditions (i.e., Standardized and Tailored)
Phase 2 (Months 8 – 38)

5-Month Active Implementation. One office professional per site will be invited to participate on the implementation team at each site. The implementation team consists research team members, site administrator, 2-4 clinician opinion leaders and champions, a client, and office professional. This team will convene for triweekly meetings during the 5-month active implementation phase and they are encouraged to meet without the researchers present during the 10-month follow-up period to facilitate identification of additional barriers (the number of actual meetings and attendance will be documented). Office professionals will be informed that the consultation and training sessions will be audio-recorded for research team coding purposes, with the focus on capturing the barriers that emerged and the function of the discussions. Office professionals will be reminded at the beginning of each session not to use client names during consultation sessions to protect client confidentiality. Audio-recorded sessions will be transcribed using the procedures outlined for the focus groups. No office professional study participant identifying information will be retained in the transcripts and only 6-digit anonymous identification numbers will be used. The form found in Appendix B (MBC Barriers Coding Form; Appendix B.1) will be completed by implementation teams during their triweekly meetings; deidentified MBC Barriers Coding Forms will be analyzed for the purposes of research. Finally, a battery of surveys will be administered in-person and completed by those on the implementation teams at 5-months and 15-months during an implementation team meeting. These surveys include the Acceptability, Feasibility, Appropriateness for Implementation Teams and Conditions (Lyon, 2011; Appendix A.16-1, A.16-2); Mendel Implementation Team Survey (A.19), and Edmondson Team Measure (Edmondson et al, 1999; A.20). These surveys will take about 25 minutes to complete and staff on the implementation team will receive $15 in compensation per assessment point. Additionally, all office professionals will be invited to participate in the study by completing parts of the abbreviated baseline battery that are applicable to their position at the baseline. The battery will take about 30 minutes to complete and office professionals will be compensated $20 for completing the battery at each of the three assessment point. They will complete the battery at the same time points as clinicians: at baseline, at the 5-month follow up and 10 months following the active implementation period.

Staff: Across Both Conditions (i.e., Standardized and Tailored)
Phase 2 (Months 8 – 38)

5-Month Active Implementation. Beginning at month eight, all staff will engage in parts of the abbreviated version of the baseline battery of self-reports that are applicable to their position. For example, case managers might not complete the Progress Monitoring Theory of Planned Behavior Measure (Francis et al., 2004; Appendix A.2) because they do not have the option of doing progress monitoring with clients but psychiatrists might have this option and would therefore fill out this measure. All questionnaires will be completed online using assessment software by emailing them a link or via hard copy (in-person). The battery will take about 15 minutes to complete and staff will be compensated $20 for completing the battery at each of the three assessment points. Additionally, they will receive $1 when a paper version of the baseline is sent as an added incentive to complete the survey. They will complete the battery at the same time points as clinicians: at baseline, at the 5-month follow up, 10 months following the active implementation period.

SECTION VIII: RISK/BENEFIT RATIO

POTENTIAL RISKS

Given the existence and ongoing oversight of Centerstone Research Institute for all research conducted at Centerstone, the investigative team has considerable experience conducting research of the proposed nature without problem. The questionnaires, focus group, and individual interview approaches proposed in this study are based on established procedures used in a wide range of studies without adverse effects. Even so, we acknowledge several potential risks that may occur as a result of clinician, client, site administrator, and office professional study participation and have established appropriate procedures for minimizing these risks, which include: (a) loss of confidentiality; (b) experience of discomfort answering questions (for clinicians, site administrators, and office professionals regarding their work at Centerstone and for clients in reporting their experience with depression in the presence of a research assistant), and (c) the potential for clinicians, site administrators, staff and office professionals to perceive coercion to participate in the study given that this proposal aligns with the agency's overall strategic goals. To address the risk of loss of confidentiality, a database file connecting clinician, site administrator, staff, and office professional identification numbers and names will be located at Indiana University and will be password protected and stored on a locked computer accessible only to trained research staff. In addition, due to the potential loss of confidentiality through audiotaped sessions review, clients and

clinicians will have the opportunity to request their sessions not be audiotaped and used for research purposes. If clients and clinicians do agree to their audiotapes being used for research purposes, they are assured that the objective coders would remove themselves should they recognize a subject's voice and that all coders are trained to maintain confidentiality of content reviewed in the audiotape. To address the risk of clinicians, site administrators, office professionals, staff, and clients experiencing discomfort, research staff will be trained to address distress during focus groups, individual interviews, and assessment procedures. Finally, we are engaging explicit procedures to protect against the risk of perceived coercion of participating clinicians, site administrators, and office professionals (described in Section IX).

POTENTIAL BENEFITS

Clinicians

Clinicians who choose to enroll in the study will have the opportunity to receive training in the use of measurement-based care (MBC), an evidence-based practice framework. We hope that this training opportunity will enable clinicians to enhance their client care by providing them with an additional tool for monitoring client progress throughout treatment and for assessing client treatment outcomes. Clinicians will also receive Continuing Education Units (needed for licensure) for attending the training. In addition, clinicians may benefit from the enhanced Electronic Health Record system equipped with the PHQ-9 and a clinician-informed optimal user interface.

Clients

Clients who choose to enroll in the study will have the opportunity to receive mental health care from a clinician who has received training in the use of MBC, thus providing the potential for the client to receive enhanced treatment as usual. Furthermore, previous research has indicated that MBC can result in improved client satisfaction and engagement in treatment (Eisen, Dickey, & Sederer, 2000). Beyond the potential for enhanced care, clients enrolled in the study will receive treatment for depression as usual at Centerstone. In sum, we believe that the potential benefits of this study outweigh the potential risks.

Administrators

Administrators who choose to enroll in the study will have the opportunity to assist in the implementation of measurement-based care in his or her site. Their involvement is consistent with a community participatory approach that elevates their voice and values in the implementation process.

Office Professionals

Office professionals who choose to enroll in the study will have the opportunity to assist in the implementation of measurement-based care in his or her site. Their involvement is consistent with a community participatory approach that elevates their voice and values in the implementation process.

Staff

Staff who choose to enroll in the study will have the opportunity to make their voices and values heard in the implementation process by filling out brief batteries of surveys.

Few experimental implementation studies have been conducted. Findings from this proposal have the potential to: (1) yield a robust theoretical and practical model delineating contextual factors and evaluative processes for implementation in an academic-community partnership; (2) demarcate the benefit of using standardized versus tailored protocols for implementation; (3) establish a blended protocol for MBC implementation with capacity for generalization to community mental health centers nationwide; and, (4) highlight contextual factors responsible for sustained MBC implementation. With depression maintaining its place among the nation's top chronic illnesses, costing billions of dollars annually, positive findings from this proposal will present a feasible and effective approach to alleviating great societal burden through a minimal intervention needed for change. This study will lay the groundwork for subsequent research (by establishing progress monitoring) to enhance usual care for multi-problem clinical presentations, should MBC effects plateau and additional interventions be necessary.

Due to the minimal risks for this study protocol and the potential gains for clinicians with respect to professional development and potential positive client symptom outcomes, we believe that the benefits of this protocol outweigh the risks.

SECTION IX: PROTECTION PROCEDURES

Clinicians

Given the study procedures presented above, we believe that the study presents minimal risk to clinician participants. For enrolled clinicians, all data collection will be completed by trained research staff and all data will be kept in secure locations at either

Centerstone Research Institute or at Indiana University. Data, both quantitative (questionnaires) and qualitative (focus group transcripts) will be associated with an anonymous 6-digit research identification number for each participant. Data completed via the online Qualtrics survey will be stored in secure databases on password-protected computers at Indiana University. All audio-recorded focus groups and consultation meetings will be transcribed by research staff members trained in confidentiality procedures by the PI or via a voice transcription and indexing company, VoiceBase, Inc. All identifiers will be removed at the time of the transcription and replaced with the participant code. VoiceBase, Inc. provides a human transcription service for audio recordings. This company follows a strict privacy policy that attempts to maintain the utmost confidentiality of all transcriptions. As mentioned, researchers (objective coders) who will review the audiotaped sessions will be trained to maintain confidentiality and these audiotapes will be securely locked up and kept in secure locations.

Another potential risk could be differential treatment by clinical supervisors based on the knowledge of the clinicians' participation in the study. It is not possible to conceal clinician study participation from supervisors. However, each supervisor will be instructed in human subjects research protections and made aware of the seriousness of research participant coercion in any form. Further, the supervisors and their managers will be instructed not to use participation in research as criteria for adjustment of wages or job position. The clinician participant will be made aware of this risk and given the contact numbers of the compliance office at Indiana University to report any unfair treatment based on their participation, or lack of, in research. Moreover, even though we plan to randomize at the site level, not all clinicians at each site will need to participate in order for recruitment goals to be met. Therefore, clinicians will be explicitly informed that even though their site is enrolled and they may be eligible, there is no obligation to participate in the research.

We anticipate that the only other potential risk related to clinician participation in the study is possible discomfort when providing personal opinions to research personnel during focus groups and/or during completion of online questionnaires. To address this potential risk, all clinicians will be made aware of the voluntary nature of the study, and told that they may choose to end participation at any time. All clinicians will be informed about the confidential nature of the data obtained through participation and the procedures put in place to protect each participant. Clinicians will also be informed that participation in the study will in no way affect their status as a clinician at Centerstone and their individual data will not be shared with their supervisors. Additionally, clinicians will be informed that their qualitative and quantitative data will never be linked to any personal identifying information (in discussion with Centerstone, in manuscripts, presentations, etc.) beyond the securely kept code sheet at Indiana University and at Centerstone with the CRI RAs used for keeping participant identification numbers consistent over time (to enable within-subjects evaluation).

Clients

We believe that the proposed study presents minimal risk to client participants. Clients who choose to participate in the study will be complete their baseline PHQ-9 assessment and week 12 assessment on the phone with the research assistant, trained to response to signs of distress, during the consenting phone call. In addition, PHQ-9 assessments completed prior to a session will be completed via hard copy forms in the waiting room. The potential risks for clients will be the possibility of discomfort when sharing information regarding mental health status with the research staff member, and the potential for a breach of confidentiality. To address these potential risks, all clients will also be made aware of the voluntary nature of the study and that they may also choose to end participation at any time. They will also be made aware of the extra provisions for protection of confidentiality afforded them by the NIH approved Certificate of Confidentiality in their informed consent document. Hundreds of studies to date have successfully used the PHQ-9 with clients; it is the most widely used depression severity measure. Centerstone has established procedures for handling client distress during a baseline and week 12 assessment. Specifically, research personnel conducting baseline and week 12 assessments will be trained to be sensitive to signs of distress (e.g., psychomotor agitation, avoidance of responding to questions) and to respond appropriately (i.e., ask the client if they would like to end or continue the assessment). Moreover, research personnel conducting assessments will be trained to seek consultation with a licensed mental health professional in the event that a client displays distress during the baseline and week 12 assessment. PI, Dr. Lewis, is a licensed clinical psychologist and will be on call by cell phone should research personnel need consultation regarding observed client distress. In the rare event that the study PI is unavailable, the interviewer will be instructed to consult with one of the clinic directors who are all licensed clinical psychologists or with a designated on-call clinician present at each clinic. Baseline and week 12 assessments will always be conducted during business hours when an on-call licensed mental health professional is available. Given the similarity of the PHQ-9 questions to a portion of the typical intake interview at Centerstone, on-call clinicians are well-versed in dealing with any distress that might arise. In particular, research personnel will be trained to conduct comprehensive suicide risk assessments given the potential for comorbid depression and suicidal ideation. Specifically, research assistants conducting baseline and week 12 assessments will check item 9 of the PHQ-9 during the baseline and week 12 assessment call. If suicidality is endorsed (anything greater than a 0 on #9 of the PHQ-9 endorsed), research assistants will then ask the client questions on the Columbia-Suicide Severity Rating scale (C-SSRS; Research Foundation for Mental Hygiene, Inc., 2008; Appendix D.2). If the client then endorses #'s 2-6 on the screener then the researcher will engage in the pre-established comprehensive risk assessment and the consultation plan (i.e., contacting the Centerstone crisis line while the client is still on the phone) described above. All research assistants will be required to complete an Adverse Event Report Form (Appendix D.1) to be submitted to the study PI within 24 hours of the incident. This form requires the research assistant to detail the client's distress, the research assistant's actions, consultation if engaged, and any follow-up plan that was developed. If necessary these forms will be used to follow-up with clients, and will be reviewed by the Data Safety Monitoring Board on an ongoing basis in order to assess the overall distress experienced by participants throughout the study. The above-listed protocol will be reviewed in Phase 1 (prior to client enrollment)

with the Data Safety and Monitoring Board, and if needed, it will be revised to reflect the optimal plan for client safety during participation in the research protocol.

Finally, exhaustive efforts to ensure the maintenance of confidentiality will be implemented: all client data collection throughout the study will be conducted by trained research personnel, will only be labeled with anonymous 9-digit research identification numbers, and will be kept in locked cabinets at both the Centerstone and Indiana University research sites and stored in secure, password protected databases on password protected computers accessible only to study research personnel. As mentioned, researchers (objective coders) who will review the audiotaped sessions will be trained to maintain confidentiality and these audiotapes will be securely locked up and kept in secure locations.

Administrators

We believe that the study presents minimal risk to administrator participants. For enrolled administrators, all data collection will be completed by trained research staff and all data will be kept in secure locations at either Centerstone Research Institute or at Indiana University. Data, both quantitative (questionnaires) and qualitative (individual interview transcripts) will be associated with an anonymous 6-digit research identification number for each participant. Data completed via the online Qualtrics survey will be stored in secure databases on password-protected computers at Indiana University. All audio-recorded individual interviews and consultation meetings will be transcribed by research staff members trained in confidentiality procedures by the PI or via a voice transcription and indexing company, VoiceBase, Inc. All identifiers will be removed at the time of the transcription and replaced with the participant code. VoiceBase, Inc. provides a human transcription service for audio recordings. This company follows a strict privacy policy that attempts to maintain the utmost confidentiality of all transcriptions.

Another potential risk could be differential treatment by more superior administrators or supervisors based on the knowledge of the administrators' participation in the study. Although it is not possible to conceal administrator study participation from supervisors, each supervisor will be instructed in human subjects research protections and made aware of the seriousness of research participant coercion in any form. Further, the supervisors will be instructed not to use participation in research as criteria for adjustment of wages or job position. The administrator participant will be made aware of this risk and given the contact numbers of the compliance office at Indiana University to report any unfair treatment based on their participation, or lack of, in research. Administrators will be explicitly informed that even though their site is enrolled and they may be eligible, there is no obligation to participate in the research.

We anticipate that the only other potential risk related to administrator participation in the study is possible discomfort when providing personal opinions to research personnel during individual interviews and/or during completion of online or hard copy questionnaires. To address this potential risk, all administrators will be made aware of the voluntary nature of the study, and told that they may choose to end participation at any time. All administrators will be informed about the confidential nature of the data obtained through participation and the procedures put in place to protect each participant. Administrators will also be informed that participation in the study will in no way affect their status as an administrator at Centerstone and their individual data will not be shared with their supervisors. Additionally, administrators will be informed that their qualitative and quantitative data will never be linked to any personal identifying information (in discussion with Centerstone, in manuscripts, presentations, etc.) beyond the securely kept code sheet at Indiana University and at Centerstone with the CRI RAs used for keeping participant identification numbers consistent over time (to enable within-subjects evaluation).

Office Professionals

We believe that the study procedures present minimal risk to office professional participants. For enrolled office professionals, all data collection will be completed by trained research staff and all data will be kept in secure locations at either Centerstone Research Institute or at Indiana University. Data, both quantitative (questionnaires) and qualitative (consultation transcripts) will be associated with a 6-digit anonymous research identification number for each participant. Data completed via the online Qualtrics survey will be stored in secure databases on password-protected computers at Indiana University. All audio-recorded consultation meetings will be transcribed by research staff members trained in confidentiality procedures by the PI or via a voice transcription and indexing company, VoiceBase, Inc. All identifiers will be removed at the time of the transcription and replaced with the participant code. VoiceBase, Inc. provides a human transcription service for audio recordings. This company follows a strict privacy policy that attempts to maintain the utmost confidentiality of all transcriptions.

Another potential risk could be differential treatment by supervisors based on the knowledge of the office professionals' participation in the study. It is not possible to conceal office professional's study participation from supervisors. However, each supervisor will be instructed in human subjects research protections and made aware of the seriousness of research participant coercion in any form. Further, the supervisors and their managers will be instructed not to use participation in research as criteria for adjustment of wages or job position. The office professional participant will be made aware of this risk and given the contact numbers of the compliance office at Indiana University to report any unfair treatment based on their participation, or lack of, in research. Office professionals will be explicitly informed that even though their site is enrolled and they may be eligible, there is no obligation to participate in the research.

We anticipate that the only other potential risk related to office professional participation in the study is possible discomfort when providing personal opinions to research personnel during completion of online or hard copy questionnaires. To address this potential risk, all office professionals will be made aware of the voluntary nature of the study, and told that they may choose to end participation at any time. All office professionals will be informed about the confidential nature of the data obtained through participation and the procedures put in place to protect each participant. Office professionals will also be informed that

participation in the study will in no way affect their status as an office professional at Centerstone and their individual data will not be shared with their supervisors. Additionally, office professionals will be informed that their qualitative and quantitative data will never be linked to any personal identifying information (in discussion with Centerstone, in manuscripts, presentations, etc.) beyond the securely kept code sheet at Indiana University and at Centerstone with the CRI RAs used for keeping participant identification numbers consistent over time (to enable within-subjects evaluation).

Staff

We believe that the study procedures present minimal risk to staff participants. For enrolled staff, all data collection will be completed by trained research staff and all data will be kept in secure locations at either Centerstone Research Institute or at Indiana University. Data will be associated with a 6-digit anonymous research identification number for each participant. Data completed via the online Qualtrics survey will be stored in secure databases on password-protected computers at Indiana University.

Another potential risk could be differential treatment by supervisors based on the knowledge of the staff members' participation in the study. It is not possible to conceal staff members' study participation from supervisors. However, each supervisor will be instructed in human subjects research protections and made aware of the seriousness of research participant coercion in any form. Further, the supervisors and their managers will be instructed not to use participation in research as criteria for adjustment of wages or job position. The office professional participant will be made aware of this risk and given the contact numbers of the compliance office at Indiana University to report any unfair treatment based on their participation, or lack of, in research. staff will be explicitly informed that even though their site is enrolled and they may be eligible, there is no obligation to participate in the research.

We anticipate that the only other potential risk related to staff member participation in the study is possible discomfort when providing personal opinions to research personnel during completion of online or hard copy questionnaires. To address this potential risk, all staff members will be made aware of the voluntary nature of the study, and told that they may choose to end participation at any time. All staff members will be informed about the confidential nature of the data obtained through participation and the procedures put in place to protect each participant. Staff members will also be informed that participation in the study will in no way affect their status as clinical staff at Centerstone and their individual data will not be shared with their supervisors. Additionally, staff will be informed that their data will never be linked to any personal identifying information (in discussion with Centerstone, in manuscripts, presentations, etc.) beyond the securely kept code sheet at Indiana University and at Centerstone with the CRI RAs used for keeping participant identification numbers consistent over time (to enable within-subjects evaluation).

Clinician, Administrator, Office Professional and Staff confidentiality

For enrolled clinicians, administrators, office professional, and staff all data collection will be completed by trained research staff and all data will be kept in secure locations at either Centerstone Research Institute or at Indiana University. Data, both quantitative (questionnaires) and qualitative (focus group transcripts, consultation transcripts, and individual interview transcripts) will be associated with an anonymous 6-digit research identification number for each participant. Data completed via the online survey will be stored in secure databases on password-protected computers at Indiana University. Any hard copies of data (should clinicians, administrators, staff, and/or office professionals complete surveys in person) will be transferred to an electronic database; hard copies will be kept in locked cabinets in locked rooms and destroyed at the end of the funding period.

Client confidentiality

All client data collection throughout the study will be conducted by trained research personnel, will only be labeled with anonymous 9-digit research identification numbers, and will be kept in locked cabinets at both the Centerstone and Indiana University research sites and stored in secure, password protected databases on password protected computers accessible only to study research personnel.

Ensuring security and feasibility of automated telephone surveys.

Automated telephone surveys will be employed to assess MBC fidelity (using a yes/no/did not attend session option regarding clinician discussion of the PHQ-9 measure with the client) throughout the study. The automated telephone survey will be set to text or call the enrolled study clients in advance of each scheduled psychotherapy session with the enrolled clinician based on a code triggered by the Electronic Health Record.. Frequency of use of mobile technologies is increasing for assessment and intervention, with data suggesting that underserved and disadvantaged populations are typically owners of mobile phones making this a feasible data collection method (Foley et al., 2012). Additionally, automated telephone surveys serve as a secure and confidential way for clients to respond to the MBC fidelity questions as the client can respond with their touch-tone keypad, thus ensuring that question content and responses remain private and confidential. It is unlikely that enrolled Centerstone clients will not own a telephone; however, in these rare cases (determined during the initial screening/consenting process) the Centerstone research assistants will schedule to meet the client on-site for hard copy administration of the PHQ-9.

SECTION XI: PAYMENT FOR PARTICIPATION

A. Will subjects be paid for participation in the study (e.g. monetary, free services, gifts, course credit, including extra credit)?

☐ No. Proceed to next section.

☒ Yes. Complete items 1-3 below.

1. Explain the payment arrangements (e.g. amount and timing of payment and the proposed method of disbursement), including reimbursement of expenses.

Clinicians

We will compensate clinicians $25 for participation in the 1.5 hour focus group held at the beginning of the active implementation, end of the active implementation, and end of Phase 2 of the study. Quantitative questionnaires will be completed at baseline, 5-months, and 15-months and clinicians will be provided $50 for each assessment completed in compensation for the time required to complete study measures. Those clinicians on the implementation team will complete a battery of quantitative questionnaires at 5-months and 15-months and will receive $15 in compensation per assessment point. At sites affected by technology issues, clinicians will be compensated $1 for each time they answer questions related to PHQ-9 use with clients (see Appendix B.4). In addition, at the beginning of Phase 2 of the study, clinicians will be asked to participate in one four-hour training session that will introduce either the standardized MBC approach or the tailored MBC procedures. Clinicians will receive Continuing Education Units (i.e., education credit needed for licensure) for attending the training. An additional battery of quantitative measures will be completed post-training and clinicians will be provided $10 in compensation. Clinicians who participate in the exit interviews at 5 month end of active implementation period will receive $20.

Clients

All clients who complete the baseline (i.e., initial phone screen) PHQ-9 assessment, regardless of study eligibility, will be mailed an incentive of $5 for completing the baseline assessment and another $5 for returning signed study documents. Clients who complete the week 12 PHQ-9 assessment will be mailed a $10 incentive for completing it. Client can earn $2 for every phone-based survey they complete for up to $20. So clients may be able to earn an additional $20 for completing these text messages after each session and this amount attained will be mailed with the $10 incentive for completing the week 12 PHQ-9 (described below). In addition, if a client does not have unlimited text messaging, we will offset the costs for the text message surveys by providing the client with $5. Clients who participate in the three implementation team meetings will receive $15 per meeting attended.

Administrators

All administrators who complete the individual interview will be compensated $20. Those administrators on the implementation team who complete a battery of quantitative questionnaires at 5-months and 15-months and will receive $15 in compensation per assessment point. Administrators will receive $50 compensation for completing the battery at the three time points: baseline, at 5-month follow up, and at 10-month follow up.

Office Professionals

Those office professionals on the implementation team who complete a battery of quantitative questionnaires at 5-months and 15-months and will receive $15 in compensation per assessment point. All office professionals will be receive $20 compensation for completing the abbreviated battery at the three time points: baseline, at 5-month follow up, and at 10-month follow up

Staff

Staff will receive $20 compensation for completing the abbreviated battery at the three time points: baseline, at 5-month follow up, and at 10 months after active implementation. When a paper version of the baseline is sent, an additional $1 incentive will be included.

2. Justify the proposed payment arrangements described in section B. (e.g., how this proposed payment arrangement is not considered to be coercive).

Clinicians

Centerstone clinicians make an average of $23.5/hour; therefore, this compensation amount is appropriate for the time and effort required for measure completion and focus group participation. The continuing education credits received for attending the MBC training are meant to directly offset the costs of participating.

Clients

Clients will receive $10 for each completed PHQ-9 assessment across two time points (over the phone at intake, and via phone in week 12 of treatment). This payment is meant as an incentive to complete the PHQ-9 assessment. An additional $20 may be earned by completing the phone based messaging survey after each session, which is meant as incentive to complete the text messaging surveys. No compensation/incentive will be provided for client PHQ-9 completion prior to other sessions in order to maximize external validity (i.e., mimic the "real world" situation in which MBC would otherwise be expected to occur without compensation) and to facilitate sustainment

Administrator

Administrators will receive $30 for completing an individual interview, $15 per assessment completed as part of participating on the implementation teams and $20 for completing the abbreviated battery. We believe these amounts are appropriate for the time and effort required to participate in the individual interviews and complete the battery of questionnaires.

Office Professionals
Office professionals will receive $15 per assessment completed as part of participating on the implementation teams and $20 per abbreviated battery completed. This payment is believed to be an appropriate amount for the time required to complete the battery of questionnaires.

Staff
Staff will recieve $20 per abbreviated battery completed. This payment is believed to be an appropriate amount for the time required to complete the battery of questionnaires. Staff will receive $1 when they receive the paper version of the survey. This payment is believe to an appropriate additional incentive to complete the paper version of the survey.

3. Explain if there will be any partial payment if the subject withdraws prior to completion of the study (e.g. prorated). Note: This payment may be paid at the end of the subject's participation or at the end of the study.

   There will not be partial payment. Clinicians who complete the data collection procedures (i.e., assessments and focus groups) will receive the aforementioned compensation or continuing education credits. Similarly, clients who complete the PHQ-9 assessment at baseline and/or session 12 will receive the $10 incentive for each assessment completed. Administrators and Office professionals who complete the data collection procedures outlined above will receive the previously mentioned compensation.

SECTION XII: INFORMED CONSENT PROCESS

☒ **A. I WILL be obtaining informed consent from all subjects.**

1. **When (in what timeframe) and where (what setting) will consent take place?** Indicate any waiting period between informing the subject and obtaining consent. The timeframe and any waiting should ensure the prospective subjects or their legally authorized representatives are provided sufficient opportunity to consider whether or not to participate in the study.

   Consenting Clients
   There is one pathway to identify clients for participation in the study. For full details on the recruitment process, please see the HIPAA Recruitment Checklist. There will be one Centerstone Research Institute research assistant (CRI RA) responsible for sites located in Tennessee and one CRI RA responsible for sites located in Indiana. Centerstone Research Institute has established a system for identifying clients eligible for the various ongoing research projects. Specifically, each CRI RA will run queries of the Electronic Health Record system database daily to identify potentially eligible clients seeking individual psychotherapy for depression with enrolled study clinicians based on the above listed inclusion/exclusion criteria (all eligibility information is collected during the intake and stored in the database). The average time from intake to the first psychotherapy session at Centerstone is 13 days, which will provide ample time for eligible clients to be enrolled in the study prior to the first therapy session. However, to ensure that the potential participant is contacted in a timely manner before their first psychotherapy session, the queries will be run daily. Upon identification of potential eligibility, the CRI RAs will contact the client via telephone within 24 hours to perform an eligibility 10-20 minute phone screen. The initial phone screen (RCR.3) is to confirm eligibility for participation, which is based on having a PHQ-9 score greater than 9 and a willingness to participate in the study. The CRI RA will verbally administer the PHQ-9 (in its entirety) to confirm project eligibility. If the client is determined to be eligible, the CRI RA will go over the informed consent statement (study procedure, risks/benefits, confidentiality, etc.) and ask the client if s/he is willing to give verbal consent to participation in the study at that time or if s/he would like to first receive and review the informed consent statement and the authorization for the release of protected health information. The CRI will stress that participation is voluntary and that the client may withdraw consent at any time. Following the phone call, consented participants and those interested in consenting upon review of the informed consent statement will be mailed a Welcome Packet, which will contain the informed consent for the client's records.

   Three days after the Welcome Packet is sent out, CRI RAs will then follow up with clients by telephone so that the client may have the opportunity to ask questions about the study. At this time, the CRI RAs may also offer to visit clients in person at their local Centerstone site or in their home (only if the RA is comfortable with this option) to discuss remaining questions about the research project further. Finally, although clinicians are not formally a part of the recruitment process, we have created an information sheet for clinicians in case his or her client has questions about the study the

clinician will be able to provide some background (RCR.8) and a client study brochure (Appendix F.2) that s/he can offer the client.

Consenting Administrators

Administrators will first be sent a recruitment email with overall study information and their role in their study (RCR.5). Administrators will be consented via two pathways: 1) in person, implicit consent during the initial site visit staff meeting and 2) email recruitment with implicit consent. The implicit consent procedure is described here: 1) During a staff meeting at each site, a member of the research team will provide staff members with a welcome packet and verbally give information about the study. Food will be provided to each site administrator in attendance. The welcome packet will include a two administrator informed consent forms and the project coordinator's contact information. The research member will indicate that participation in the study is voluntary and will in no way affect their status as administrators at Centerstone. Administrators will have the opportunity to fill out the battery of measures thus giving their implicit consent to participation in person at this initial site visit or if the administrator would like to take additional time to review before filling out the battery and therefore consenting, s/he will be given a pre-paid, return-addressed envelope to mail the completed battery of measures when s/he is ready OR at the start of the next staff meeting a member of the research team will attend the first few minutes to answer questions and collect surveys. The email recruitment/ consent is detailed here: For those administrators who could not attend this staff meeting, a recruitment email (RCR.5) will be sent out to these administrators by a member of the research team with an e-version of the welcome packet for site administrators should they prefer to complete the battery of measures through an electronic survey option. Administrators may give their implicit consent to participation by filling out the baseline battery. These administrators will be contacted by CRI RAs directly to see if they have any questions or concerns about participating.

Consenting Office Professionals

Office professionals will be recruited and consented via two avenues: 1) in person, implicit consent during the initial site visit and 2) email recruitment with implicit consent. The in person, implicit consent is described here: During a staff meeting at each site, a member of the research team will provide staff members with a welcome packet and verbally give information about the study. Food will be provided to each site office professional in attendance. The site administrator will send out an email (RCR.6) with information about this site visit to the office professionals. The welcome packet will include a two office professionals' informed consent forms, study recruitment letter (RCR.7), and the project coordinator's contact information. The research member will indicate that participation in the study is voluntary and will in no way affect their status as office professional at Centerstone. Office professional will have the opportunity to fill out the abbreviated battery of measures in person at this initial site visit or if the office professional would like to take additional time to review before filling out the abbreviated battery and therefore consenting, s/he will be given a pre-paid, return-addressed envelope to mail the abbreviated battery of measures when s/he is ready OR at the start of the next staff meeting a member of the research team will attend the first few minutes to answer questions and the abbreviated battery. For those office professionals who could not attend this staff meeting, 2) the site administrator for each site will place a welcome packet in those office professionals' mailboxes. State specific CRI RAs will then individually contact (via phone or email) these office professionals after a few days to see if s/he has any questions about the consent or participation process. The email recruitment/electronic implicit consent is described here: The other option for office professional recruitment and consent is via email recruitment for those office professionals who cannot attend the initial site visit with the research team. A recruitment email will (RCR.7) be sent out to these office professionals by a member of the research team with an e-version of the welcome packet should they prefer to complete the battery of measures through an electronic survey option. These office professionals will then have the option to implicitly consent by filling out the abbreviated baseline battery. These office professionals will be contacted by CRI RAs directly to see if they have any questions or concerns about participating.

Consenting Staff

Staff will be recruited and consented via two avenues: 1) in person, implicit consent during the initial site visit and 2) email recruitment with implicit consent. The in person, implicit consent is described here: During a staff meeting at each site, a member of the research team will provide staff members with a welcome packet and verbally give information about the study. Food will be provided to each staff member in attendance. The site administrator will send out an email (RCR.9) with information about this site visit to the staff. The welcome packet will include two staff informed consent forms, study recruitment letter (RCR.7), and the project coordinator's contact information. The research member will indicate that participation in the study is voluntary and will in no way affect their status as a staff member at Centerstone. Staff will have the opportunity to fill out the abbreviated battery of measures in person at this initial site visit or if the staff member would like to take additional time to review before filling out the abbreviated battery and therefore consenting, s/he will be given a pre-paid, return-addressed envelope to mail the abbreviated battery of measures when s/he is ready OR at the start of the next staff meeting a member of the research team will attend the first few minutes to answer questions and the abbreviated battery. For those staff members who could not attend this staff meeting, 2) the site

administrator for each site will place a welcome packet in those staff members' mailboxes. State specific CRI RAs will then individually contact (via phone or email) these staff members after a few days to see if s/he has any questions about the consent or participation process. The email recruitment/electronic implicit consent is described here: The other option for staff recruitment and consent is via email recruitment for those staff who cannot attend the initial site visit with the research team. A recruitment email will containing the ICS be sent out to these staff members by a member of the research team with an e-version of the welcome packet should they prefer to complete the battery of measures through an electronic survey option. These staff members will then have the option to implicitly consent by filling out the abbreviated baseline battery. These staff members will be contacted by CRI RAs directly to see if they have any questions or concerns about participating.

2. **Who will be responsible for obtaining initial and ongoing consent? (check all that apply)**

☒ Principal Investigator
☒ Co-Investigator
☒ Other (specify): **Approved investigators, project coordinator, research assistants**

a. **Explain how these individuals will be adequately trained to conduct the consent interview and answer subject's questions (check all that apply):**

☒ Passed the required Collaborative Institutional Training Initiative (CITI) modules
☐ Attended the Research Coordinator Education Program (RCEP)
☐ Attended the Research Coordinator Certification Program (RCCP)
☒ Received study-specific training from study personnel
☒ Other (specify): HIPAA training, National Institutes of Health Human Subjects Training

b. Indicate in what language(s) the consent interview will be conducted.

☒ English
☐ Spanish
☐ Other (specify):

c. If the consent interview will be conducted in a language other than English, state how the interview will be conducted (e.g. use of an interpreter):

3. **Explain how subjects' privacy will be protected during the consent process.** This refers to how access to subjects will be controlled (e.g. time, place, etc. of consent procedures).

Clients
A research assistant will call the potential client participant and ask if they are in a private setting and whether it would be convenient to speak about their interest in participating in the study. If it is not an optimal time for the client then the research assistant will schedule a more appropriate/convenient time in which to call the client back.

Administrators
A CRI RA will give the administrator participants an opportunity to set up a separate time to offer more information and answer any questions the administrator would have at their convenience over the phone, via email, or in person at Centerstone.

Office Professionals
A CRI RA will give the office professional participants an opportunity to set up a separate time to offer more information and answer any questions the office professional would have at their convenience over the phone, via email, or in person at Centerstone.

Staff
A CRI RA will give the staff participants an opportunity to set up a separate time to offer more information and answer any questions the office professional would have at their convenience over the phone, via email, or in person at Centerstone.

1. **Indicate any factors that might result in the possibility of coercion or undue influence. (check all that apply)**

☐ the research will involve students of the investigator(s)
☐ the subjects will be recruited through institutions with which the PI has a close relationship
☒ Other (please specify): potential for clinicians to perceive coercion to participate in the study given that this proposal aligns with the agency's overall strategic goals.

Describe steps taken to mitigate the possible coercion: It is not possible to conceal clinician, administrator, or office professional study participation from supervisors. However, each supervisor will be instructed in human subjects research protections and made aware of the seriousness of research participant coercion in any form. Further, the supervisors and their managers will be instructed not to use participation in research as criteria for adjustment of wages or job position. The clinician, administrator, and office professional participant will be made aware of this risk and given the contact numbers of the compliance office at Indiana University to report any unfair treatment based on their participation, or lack of, in research. Moreover, even though we plan to randomize at the site level, not all clinicians at each site will need to participate in order for recruitment goals to be met. Therefore, clinicians will be explicitly informed that even though their site is enrolled and they may be eligible, there is no obligation to participate in the research.

☒ **C. I am requesting a waiver of *written documentation* of informed consent (i.e. a consent process will occur, but no signature will be obtained from the subject).**

☒ Written statement regarding the research has been attached. Statement will be provided to subjects upon their request. Please explain:

Consenting Clients

Clients will consent for participation in the study after completing the eligibility screening over the phone with a CRI RA. Once the client has been determined eligible the CRI RA will go over the informed consent statement (study procedure, risks/benefits, confidentiality, etc.) and authorization for the release of protected health information and ask the client if s/he is willing to give verbal consent to participation in the study at that time or if they would like to first receive and review the informed consent statement. The CRI will stress that participation is voluntary and that the client may withdraw consent at any time. At this time, the client may verbally consent to participation or call back after reviewing the informed consent statement. Following the phone call, consented participants and those interested in consenting upon review of the informed consent statement will be mailed a Welcome Packet, which will contain the informed consent for the clients record. After clients give their verbal consent to participation, they will be enrolled in the study and data collection can begin.

Consenting Clinicians

All clinicians who meet the inclusion criteria presented below and who provide services at any of the 12 Centerstone sites involved in the proposed research will be eligible for participation in the study. There are three pathways through which the clinicians will be recruited and one way they may consent to participate in the research. The research team will recruit clinicians for participation via email and site visits.

Recruitment Option 1: During a staff meeting at each site, a member of the research team will provide staff members with a welcome packet and verbally give information about the study. One hour of productivity credit coverage and food will be provided to each clinician in attendance. The site administrator will send out an email (RCR.1) with information about this site visit to the clinicians. The welcome packet will include two Clinician informed consent forms, a study recruitment letter (RCR.2), the baseline battery of questionnaires, and the project coordinator's contact information. The research member will indicate that participation in the study is voluntary and will in no way affect their status as clinicians at Centerstone. The recruitment letter as well as the research member(s) present at the meeting will inform clinicians that by filling out and returning the baseline battery of questionnaires to the researchers, s/he is agreeing to participate in the research project and all of its activities. However, if the clinician would like to take additional time to review the informed consent before implicitly consenting, s/he will be given a pre-paid, return-addressed envelope to mail the filled out baseline battery of questionnaires when s/he is ready OR at the start of the next staff meeting a member of the research team will attend the first few minutes to answer questions and collect the filled out battery of questionnaires.

Recruitment Option 2:

For those clinicians who could not attend this staff meeting, the site administrator for each site will place a welcome packet in the clinician mailboxes of those who could not attend. A research member will then individually contact (via phone or email) these clinicians after a few days to see if s/he has any questions about the consent or participation process.

Recruitment Option 3: The other option for clinician recruitment and consenting is via email recruitment for those clinicians who cannot attend the initial site visit with the research team. A recruitment email (RCR.2 [the bottom portion will be revised for email recruitment]) will be sent out to these clinicians by a member of the research team with an e-version of the welcome packet should they prefer to complete the battery of measures through an electronic survey option. This

recruitment email will have a link to the web-based survey of the baseline battery of questionnaires. Upon accessing the web-based survey, study participants will be presented with a web page containing the informed consent and will be informed that clicking the "proceed" button will be taken as implicit consent to the participate in the study and all its activities. This page will include the contact information of the research team, so participants may contact the researchers with any questions they may have. In addition, these clinicians will be contacted by a research member directly after being sent the recruitment email to see if they have any questions or concerns about participating.

Consenting Administrators

Administrators will give their implicit consent for participation in the study by filling out the abbreviated baseline survey during the initial site visit. This implicit consent will be made clear verbally by a member of the research team during the visit and in the written recruitment materials and informed consent statement. See question A1. for full details of the informed consent process.

Consenting Office Professionals

Office processionals will give their implicit consent for participation in the study by filling out the abbreviated baseline survey during the initial site visit. This implicit consent will be made clear verbally by a member of the research team during the visit and in the written recruitment materials and informed consent statement. See question A1 for full details of the informed consent process.

Staff

Staff will give their implicit consent for participation in the study by filling out the abbreviated baseline survey during the initial site visit. This implicit consent will be made clear verbally by a member of the research team during the visit and in the written recruitment materials and informed consent statement. See question A1 for full details of the informed consent process.

☒ 2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Please explain:

Because the research intends to remove identifiers in the data collection process, there is minimal risk to clinicians, clients, administrators, office professional and general staff. Per NIH requirements, we propose to make the quantitative data available for secondary data analysis, but careful removal of identifiers will occur prior to making these datasets available. Rather, participation in a study of this nature (implementation of measurement-based care) suggests a clinician's client may benefit from improved treatment outcomes. Moreover, tracking client symptoms using a measurement-based care is a normal clinic procedure in many clinics and receiving training in measurement-based care and continuing education credits will likely benefit the clinician's skills and expertise. Centerstone is trying to adopt this practice, so we will just be receiving de-identified data for research purposes to evaluate the effectiveness of the implementation process. Moreover, not all of the clinicians will be able to attend the staff meeting when the initial site visit will occur, making collecting face-to-face informed consent for 187 clinicians across 12 sites and two states (Indiana and Tennessee) for whom we will not be collecting identifiable information is not feasible. In addition, requiring clinicians to schedule a unique face-to-face individual meeting with a research assistant to provide written consent is unnecessary particularly given the data will be coded so identification will not be possible.

It is also unfeasible to collect written consent from clients because this study involves the recruitment of 625 clients across 12 Centerstone sites scattered (often great distances) across Tennessee and Indiana. It is impossible for our two Centerstone Research Institute research assistants (CRI RAs) to meet clients at the clinic to collect signed consent documents in person. Furthermore, it is not possible to properly train clinicians at each site to consent clients nor do we want to add this burden to clinicians' already full workload. It is also difficult to collect signed consent forms from clients in the mail do to the nature of depression which all eligible clients have a part of their diagnosis. Specifically, depression is associated with a loss of interest in activities, difficulty concentrating and fatigue, all which interfere with daily functioning. Therefore, clients interested in participation in the study may be prevented from doing so due to the nature of their diagnosis and tedious, time consuming procedure of consenting to participate which would involve reviewing and signing multiple forms and then returning them in the mail. Thus, waiving written documentation of informed consent improves feasibility and promotes recruitment rates and will likely benefit participating clinicians and clients.