Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths
Patient-Centered Outcomes Research Institute (PCORI) Contract #IHS-1503-28573
ClinicalTrials.gov #NCT02990000
The Study Protocol
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Table of Contents

A. Full original study protocol submitted to, and approved by, the University of Massachusetts Amherst Institutional Review Board (November 2016)

PROTOCOL
APPLICATION FORM
SOCIAL, BEHAVIORAL, AND EDUCATIONAL FULL BOARD
HUMAN SUBJECTS IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL RESEARCH

University of Massachusetts Amherst (UMass)
Institutional Review Board (IRB)

Protocol ID: 2016-3401
Title: Enhancing Mental Health Care

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Human Subjects Training Completed? yes

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Subject Populations(s) Checklist	Yes/No
Minors (under 18)	N
Pregnant Women	N
Cognitively Impaired or Decisionally Challenged	N
Older individuals (75 and over)	N
Healthy Volunteers	N
Students/Employees	N
International Populations	N
Prisoners	N
Other (i.e., any population that is not specified above)	Y

Other: Subjects will include two mental health care stakeholder groups: (1) therapists affiliated with Atrius Health's Behavioral Health Department, or Atrius-affiliated partners, who are providing outpatient psychotherapy, and (2) adult patients receiving psychotherapy for varied mental health complaints from the participating therapists. Atrius Health, a formal subcontract to UMass on this project, is an innovative health care organization serving patients in eastern and central Massachusetts.

Study Location(s) Checklist	**Yes/No**
University of Massachusetts Amherst	Y
Baystate Medical	N
University Health Services	N
Hartford Hospital	N
Other (Specify other Study Locations)	Y

Other: All study operations will be coordinated through Dr. Michael Constantino's (PI) Psychotherapy Research Lab at UMass Amherst. Subject data will be collected in multiple outpatient mental health clinics that are within the Atrius Health network proper, or a preferred partner of it. Atrius Health is a Pioneer Accountable Care Organization, and one of the largest multi-specialty practices in the US. The organization treats more than 32,000 patients a year in its behavioral health division. All treatment sites are in eastern and central Massachusetts.

General Checklist	**Yes/No**
Training Grant?	N
Funded Study (or proposal submitted to sponsor)?	Y
Cooperating Institution(s)?	Y
Federally Sponsored Project?	Y
Human blood, cells, tissues, or body fluids (tissues)?	N
Subjects will be paid for participations?	Y

Cooperating Institution(s): (1) University at Albany, SUNY (Dr. James Boswell; Co-PI and subcontract); (2) Outcome Referrals Institute, Inc. (ORI; Dr. David Kraus; Co-PI and subcontract); and (3) Atrius Health (Dr. Samuel Nordberg; Co-PI and subcontract). As part of this protocol, I would like to initiate UMass entering into an Institutional Authorized Agreement (IAA) with each of the three subcontracts. A previous IAA (for a separate project) is in place with my collaborator, Dr. Boswell, at University at Albany, SUNY. He and his research assistants have already affiliated with UMass through the Collaborative IRB Training Initiative (CITI) program. As additional personnel across the three subcontracts complete their CITI training (as part of the project start-up period), I will submit their names and CITI certificates as formal changes to this protocol.

Funding Checklist

Grants/Contracts:

Funding Administered By: UNIVERSITY
PGCA#: 1503-28753
GAID#:
Funded By: Patient-Centered Outcomes Research Institute
1828 L Street, NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700 | Fax: (202) 355-9558
info@pcori.org
Principle Investigator: Michael J. Constantino
Grant/Contract Title: Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths

Are the contents of this protocol the same as described in grant/contract proposal? Y
Is this a training grant? N
Are any subcontracts issues under this grant? Y

Fellowships – None
Gift Funding – None
Dept. Funding – None
Other Funding – None

1. Purpose of the study

a. Provide a brief lay summary of the purpose of the study.
Research has shown that mental health care (MHC) providers differ significantly in their ability to help patients. In addition, providers demonstrate different patterns of effectiveness across symptom and functioning domains. For example, some providers are reliably effective in treating numerous patients and problem domains, others are reliably effective in some domains (e.g., depression, substance abuse) yet appear to struggle in others (e.g., anxiety, social functioning), and some are reliably ineffective, or even harmful, across patients and domains. Knowledge of these provider differences is based largely on patient-reported outcomes collected in routine MHC settings.

Unfortunately, provider performance information is not systematically used to refer or assign a particular patient to a scientifically based best-matched provider. MHC systems continue to rely on random or purely pragmatic case assignment and referral, which significantly "waters down" the odds of a patient being assigned/referred to a high performing provider in the patient's area(s) of need, and increases the risk of being assigned/referred to a provider who may have a track record of ineffectiveness. This research aims to solve the existing non-patient-centered provider-matching problem.

Specifically, we aim to demonstrate the comparative effectiveness of a scientifically-based patient-provider match system compared to status quo pragmatic case assignment. We expect in the scientific match group significantly better treatment outcomes (e.g., symptoms, quality of life) and higher patient satisfaction with treatment. We also expect to demonstrate feasibility of implementing a scientific match process in a community MHC system and broad dissemination of the easily replicated scientific match technology in diverse health care settings. The importance of this work for patients cannot be understated. Far too many patients struggle to find the right provider, which unnecessarily prolongs suffering and promotes health care system inefficiency. A scientific match system based on routine outcome data uses patient-generated information to direct this patient to this provider in this setting. In addition, when based on multidimensional assessment, it allows a wide variety of patient-centered outcomes to be represented (e.g., symptom domains, functioning domains, quality of life).

b. What does the Investigator(s) hope to learn from the study?

The goal of this project is to test the effectiveness of an innovative, scientifically-informed patient-therapist referral match algorithm based on MHC provider outcome data. We will employ a randomized controlled trial (RCT) to compare the match algorithm with commonplace pragmatic referral matching (based on provider availability, convenience, or self-reported specialty). Psychosocial treatment will remain naturalistically administered by varied providers (e.g., psychologists, social workers) to patients with mental health concerns. We hypothesize that the scientific match group will outperform the pragmatic match group in decreasing patient symptoms and treatment dropout, and in promoting patient functional outcomes, perceived treatment credibility, outcome expectation, and care satisfaction, as well as therapeutic alliance quality. Doing so will establish the match algorithm as a mechanism of effective patient-centered MHC, and will suggest that this scientifically derived patient-provider matching intervention can be integrated into MHC systems to aid in treatment decision making, as well as increase personalization.

2. Study Procedures

a. Describe all study procedures.

We will compare the efficacy of naturalistic treatment either with or without the aid of scientific matching to a provider with a double-blind RCT. The project will involve two main phases. First, we will conduct a baseline assessment of consenting therapists' performance to determine their relative strengths and weaknesses in treating the problem domains measured by a multidimensional outcome tool. This period will establish our therapist sample pool and inform the match manipulation (a match will represent a patient being assigned to a therapist who has empirically

demonstrated during the baseline phase that he or she is stably effective at treating patients with the same presenting complaint).

Second, and after the baseline period, new consenting outpatients will be randomly assigned to the match (experimental) or no match (control) condition. Participating clinic administrators will collaborate with the research team to apply the randomization protocol. Treatment outcome will be assessed through the patient's actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after the point of termination on a randomly selected subsample). Outside of being matched to a therapist from a short-list of providers who have demonstrated (during the phase 1 baseline) reliable success in treating the patient's primary problem area, and completing study-specific measures for which participants will receive monetary compensation, treatment will be delivered as usual (the short list still allows for pragmatic considerations like availability and administrator assignment options). Additional methodological details follow.

Phase 1: To inform the match condition, we will first conduct a 6-month baseline assessment of participating therapists' performance (across 15 new cases each) to determine their strengths in treating behavioral health domains measured by the primary outcome measure on which the match algorithm is based – the Treatment Outcome Package (TOP; Kraus, Seligman, & Jordan, 2005), described below in the listing of relevant phase 1 attachments to this protocol. Developed and processed by our Co-PI (Dr. Kraus) and his subcontractor company, Outcome Referrals, Inc. (ORI), the TOP will be administered across the Atrius provider network and its preferred partners; as Atrius' care model already incorporates routine outcomes monitoring, we can leverage the existing infrastructure within this practice-based research network to support this study with little to no extra burden on administrators, providers, and patients. Being assigned 15 new cases in a 6-month baseline period is readily achievable for the fulltime therapists in the network.

Our target sample is 44 therapist participants and each therapist's next 15 patients assigned after consenting to participate in the study. Therapists will be psychologists, social workers, and licensed mental health counselors. Recruitment will be coordinated among our UMass-employed project coordinator (PC), clinic staff members, and clinic administrators, and will involve presenting information about the study (both phases 1 and 2) to providers through flyers, verbal script, or email (included as phase 1 attachments to this protocol). Interested therapist participants will meet or speak via teleconference with the PC to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed (this all occurs prior to the baseline period for establishing TOP "report cards" that will inform the match in phase 2). Therapists will be told that the study is examining various referral processes that will not affect

their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the study-specific assessments in which their study patients will engage in both phase 1 and phase 2 (though they will not have access to these research data at any time). Therapists will also need to consent to completing a few study-specific measures at phase 1 baseline and throughout treatment with each patient during the phase 2 RCT (these are described below in the listing of relevant phase 2 attachments to this protocol) For phase 1, therapists will be compensated with a $20 Amazon gift card for a one-time completion of the phase 1 baseline forms. For phase 2, they will be compensated $50 per patient (again in the form of Amazon gift cards) for completing several measures of therapy process at multiple points throughout each patient's treatment.

During phase 1, patients will only be engaged in the study by virtue of registering into the TOP system at their treatment baseline, and completing the TOP at baseline, week 8, and their termination point or week 16, whichever comes sooner (to mimic the definition of treatment outcome in the RCT phase discussed below). Given their involvement in this one element of the research protocol, patients will need to give the staff at their clinic verbal consent to be contacted by the PC or research assistant (RA). The staff members will collaborate with the research team to track these patients being treated by study-consenting therapists during this phase 1 part of the entire study. Once contacted via telephone, the PC or RA will explain the nature of the patient's involvement, which will simply involve registering on the TOP system, and completing the TOP main outcome measures at baseline, week 8, and termination. The patient will then be directed to a secure online system to complete their consent form and their baseline TOP forms. For the week 8 and the posttreatment TOP administrations, the PC/RA will email specific links that will direct patients to the measure (The PC/RA will also follow-up with phone call reminders if needed). The online system was developed and is maintained by our subcontractor, ORI. For this minimal time burden, patients will be entered into a raffle to win one of ten $25 Amazon gift cards. These 660 patients will be involved in phase 1 only. Thus, they will be debriefed by the PC or RA after they terminate their treatment-as-usual.

Relevant phase 1 attachments to this protocol:

(1) Therapist recruitment materials: flyers, verbal script, or email
(2) Therapist consent form and baseline phase 1 measures packet:

Provider Characteristics Form (PCF). This measure was developed by the research team to assess therapist demographic information, clinical experience, degree type, percent time seeing various patient types/diagnoses, any specialty training they

have received, and dimensional ratings of the influence of various theoretical orientations on their treatment approach.

Therapist Perceived Strengths (TPS). This measure was developed by the research team to assess therapists' beliefs about their effectiveness in treating the various TOP domains when uninformed of their data-driven TOP track record. This measure will allow us to examine how accurate therapists are in perceiving their own strengths and weaknesses.

(3) Patient phase 1 recruitment verbal script
(4) Patient phase 1 consent form and baseline phase 1 measures packet:

TOP-Consumer Registration Form (TOP-CR; Kraus et al., 2005). The TOP-CR will be used routinely during the phase 1 baseline (and the phase 2 RCT) to assess patient demographics. On this form, patients indicate their age, gender, ethnicity, marital status, income level, employment status, religious identification, education level, general health status, and medical and mental health treatment history.

TOP-Clinical Scales and Case Mix (TOP-CS & TOP-CM; Kraus et al., 2005). This is the primary measure in our study; it will be used to establish the therapist report cards during the baseline phase to inform the match manipulation in phase 2. It also tracks patient outcomes. The TOP-CS consists of 58 items assessing 12 symptom and functional (including strengths) domains (risk-adjusted for case mix variables assessed via 37 items on the companion TOP-CM, such as divorce, job loss, comorbidity): work functioning, sexual functioning, social conflict, depression, panic (somatic anxiety), psychosis, suicidal ideation, violence, mania, sleep, substance abuse, and quality of life. Global symptom severity is assessed by summing all items or by averaging the z-scores (i.e., standard deviation units relative to the general population mean) across each of the 12 clinical scales. Domain-specific symptom severity is quantified as the individual z-scores for each clinical scale using general population means and standard deviations for the conversion. The TOP-CS has been shown to have excellent factorial structure, as well as good test-retest reliability across all scales. It is sensitive to change while possessing limited floor and ceiling effects (Kraus et al., 2005). The TOP also has demonstrated good convergent validity, with scales like the Beck Depression Inventory (Beck, Steer, & Brown, 1996) and the Brief Symptom Inventory (Derogatis, 1975).

**Note: The TOP-CS and TOP-CM are the same measures that patients will complete at treatment week 8 and their termination point or week 16, whichever comes sooner.

(5) Patient phase 1 debriefing form:

This form will be appended at the end of the final of the three patient online assessments. It will provide additional information about the study and repeat contact information should patients wish to discuss the study further.

Phase 2: At the conclusion of baseline phase 1, participating therapists will each have had TOP-based report cards generated to inform matching in phase 2. The therapists themselves will not see their report cards; rather, this information will be used by the research team with regard to the match manipulation. Phase 2 marks the beginning of new patient recruitment into the RCT. The patient population will be adult men and women (age 18-65) largely referred by Atrius primary care and obstetrics/gynecology for triage and treatment through Atrius' behavioral health specialty practice. Our study target sample size is 264 patients (6 per therapist). The only non-age exclusion criterion for this study will be patients who are not the primary, informed decision-maker for their care.

Once referred into the Atrius behavioral health system per usual care process, the front desk staff at the participating clinics will ask potential patient subjects if they are interested in hearing more about the study were they to be treated within Atrius with individual outpatient psychotherapy (versus being referred out or receiving care that does not involve individual outpatient psychotherapy). Next, a triage clinician at the clinics will determine that patients make their own treatment decisions and will receive individual therapy as part of their "in-house" treatment plan; if so, the patient is study-eligible. Atrius clinic/triage staff will provide the research team with a daily list of referrals (via direct telephone contact or through a secure server) of patients who have provided verbal consent to be contacted about the study and who have been determined to be appropriate for relevant treatment within the Atrius system. The PC will then reach out to patients who provided verbal consent to be contacted.

If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a telephone diagnostic interview with a trained graduate clinical psychology RA (employed at either UMass or University at Albany). The RA will first review the study details/procedures and obtain consent through an online baseline survey to which the patient will be directed (again administered through the ORI platform). Patients will be informed that their participation in the trial will largely mimic the same treatment that they would receive if they were not participating. All patients will also be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience. Patients will be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they do request a transfer earlier, their data will not be analyzed for the study given the confound of multiple outpatient psychotherapy

providers. This will be treated as a dropout point for the sake of the trial. Patients will also be informed that they will complete all assessments that are part of their routine clinical care, as well as several study-specific measures, for which they will be compensated $50 total.

Once consent is obtained, the RAs will then administer the DSM-5 updated M.I.N.I. 7.0.2 International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al., 1988), described below in the listing of relevant phase 2 attachments to this protocol. The interviews will be audio-recorded through a secure web-conferencing platform. This will allow for subsequent review by an independent graduate RA to determine diagnostic reliability. Following the interview, patients will complete the self-report measures remaining in the online baseline survey (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems, all described below in the listing of relevant phase 2 attachments to this protocol).

After the full baseline assessment, patients will be randomly assigned to condition (scientifically informed matched vs. pragmatic match) with a participating Atrius provider. The PC, unaware of therapist baseline performance, will generate the randomization sequences using an online random generator. Understanding variability in site size/traffic, we will strive to recruit patients and providers from as many sites as possible in order to increase generalizability. Within condition, patients will be assigned sequentially to the site-specific therapists until they reach their study quota. Patients in the match condition will be assigned to therapists who have a demonstrated strength (derived from the baseline period) in treating, at a minimum, the patient's highest self-reported distress domain on the TOP-CS. Beyond the minimal match on the most elevated TOP-CS domain, our match algorithm will attempt to match patients to therapists on as many TOP-CS dimensions as possible, ultimately providing the clinics with at least several well-matched choices for assignment within the match condition. In order to preserve this level of choice for the clinics, there will be natural variability in the number of well-matched domains (some patients matched only on the minimum 1 TOP-CS domain, others matched on 2 or more domains). The match variability across both conditions will allow us to measure degree of match dimensionally as a moderator variable of our main treatment effect. Therapists will also be unaware of their patient's treatment condition (double blind), and they will treat both matched and non-matched patients (i.e., they will be crossed over the two conditions to minimize administrative disruptions). In the low-probability event that there is no therapist meeting minimal match criteria for a patient in the match condition, that patient will be removed from the primary study analyses (though will, of course, still be offered treatment-as-usual at the clinic) and replaced with the next patient where a match does exist. As described in our power analysis below, we are oversampling in order to account for these "dropouts," or removed data points.

In addition to the baseline assessments already described, patients will be assessed via online surveys at regular intervals during treatment (RAs will email hyperlinks to these surveys with reminders to complete them at the appropriate time intervals; RAs will also follow up with phone calls if needed). These during-treatment assessments will include the TOP-CS and measures of existential isolation and interpersonal problems at every odd-numbered week after the start of treatment, as well as global distress, therapeutic alliance quality, perceived treatment credibility, and outcome expectation after every even-numbered week (all measures of these constructs are described below in the listing of relevant phase 2 attachments to this protocol). During treatment, therapists will also be asked to complete their respective versions of the alliance and credibility/expectation measures (also at even-numbered weeks). RAs will email hyperlinks to these online surveys with reminders to complete them at the appropriate time intervals; RAs will also follow up with phone calls if needed.

As a reminder, in both conditions, the providers will deliver treatment naturalistically (i.e., with no manipulation or influence from the research team). For the sake of the RCT, "treatment outcome" will be considered the point at which treatment terminates, or 16 weeks, whichever comes sooner. For some patients, mutual termination will occur in response to outcome data-informed clinically significant improvement. For others, treatment will terminate at the Atrius-defined endpoint for a given individual treatment track (e.g., 16 sessions for major depression or generalized anxiety). After the 16th week, or the termination session if it comes sooner, patients will complete posttreatment measures: the TOP-CS and TOP-CM, a measure of treatment satisfaction, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems (all described below in the listing of relevant phase 2 attachments to this protocol). Therapists will also document the nature of termination (measure described below in the listing of relevant phase 2 attachments to this protocol). Also at posttreatment, as defined by the trial, patients will undergo a repeat diagnostic telephone assessment (i.e., a RA-administered M.I.N.I., as described above).

We will also conduct a follow-up outcome assessment at 1 year after the patient's own termination on a randomly selected subsample of 40 patients. Patients can easily be tracked in coordination with Atrius' health portal; further, patients will have provided consent for this follow-up contact (should they be randomly chosen for it). At this assessment point, patients will again complete online the TOP-CS and TOP-CM, the brief measure of global distress, the measure of existential isolation, and the measure of interpersonal problems.

Note that all self-report measures (for both patients and therapists) at all timepoints will be completed on Wi-Fi-connected tablets, or on home computers, through ORI's

secure web-based platform. The TOP has its own dedicated website and HIPAA-compliant, secure server, and all other study-specific measures will be integrated into the TOP administration process.

We predict that the scientific match group will outperform the no-match group to a clinically significant degree on TOP outcomes, global symptomatology, and interpersonal problems. We also expect that the match group will be more effective in promoting alliance quality and fostering more positive patient perceptions of treatment credibility and outcome expectation, all of which are established correlates (and candidate mechanisms) of positive treatment outcomes. Finally, we expect there to be less patient dropout in the match condition, and higher patient treatment satisfaction. Secondarily, we will examine 4 potential moderators of the expected between-group treatment effects on the primary TOP outcomes: (a) patient race (as it may be that the match algorithm is particularly potent, and an important responsiveness tool, for historically understudied or underrepresented patients), (b) degree of match of therapist strengths to patient problems (rated dimensionally as a ratio given that therapists can be matched on more than just the minimum 1 domain, and the elimination of harmful matches for any distressed domain reported by the patient), (c) patient distress severity, and (d) complexity of patient presenting problem. Thus, we will test if matching is only, or particularly, effective under the conditions of a central patient characteristic, a multiple domain match, and/or for patients with the most severe or complex pathology. As noted, we will also assess therapists' self-perceived strengths on the TOP domains. We expect to replicate previous literature showing that therapists are poor judges of their own efficacy, tending to underestimate negative effects and overestimate positive effects with their patients (Lambert, 2011), which would further underscore the importance of a data-driven match process.

Finally, for a subsample of stakeholders, we will conduct posttrial exit interviews (Ns = 5 patients, 5 therapists) to gather invaluable input on how to be responsive to the study findings in terms of dissemination, implementation, and policymaking, including the potential importance of integrating diagnosis, provider age, race, or gender into subsequent matching approaches. We will recruit stakeholders in order of completion until we reach our target Ns (therapists can only be involved once they have treated all 6 of their study patients). There are no other inclusion/exclusion criteria for the exit interviews; we will simply stop asking if participants are interested once we have reached our target Ns. This is consistent with the study consent forms, which clearly state that interested participants may be selected to engage in the interview.

Fully reflecting stakeholder engagement, and to eliminate any biases or power dynamics introduced by the PIs or their research staff, Advisory Board members (with appropriate credentialing for working with human subjects) will conduct the individual interviews. The PIs (Constantino & Boswell) will train 3

Advisory Board members on qualitative interviewing, and each will administer 1-2 pilot interviews as part of the training, plus 5 study interviews. The interviews will be conducted and audio-recorded via a secure webconferencing service and will last approximately 45-60 minutes. Participants will be compensated a $100 gift card for their time. RAs will transcribe the interviews, removing any identifying patient information. These RAs will also conduct qualitative analysis of these text-based data.

Relevant phase 2 attachments to this protocol:

(1) Patient phase 2 recruitment verbal script
(2) Patient phase 2 consent form and phase 2 baseline measures packet:

TOP-CRF, TOP-CS, and TOP-CM. All described previously.

Symptom Checklist-10 (SCL-10; Rosen, Drescher, Moos, & Gusman, 1999). To evaluate outcome with an index separate from the TOP (to test convergence and enhance the validity of any between-condition effects), we will also assess global distress with the SCL-10, a 10- item, well-validated and widely used self-report inventory that assesses psychological wellbeing.

Existential Isolation Scale (EIS; Pinel et al., 2014). To assess this isolation subtype, participants will complete the EIS, a 6-item scale that requires participants to rate the extent to which they agree with items such as “I often have the same reactions to things as other people around me do” (reverse-coded) and “Other people usually do not understand my experiences” and “People often have the same ‘take’ or perspective on things that I do” (reverse-coded). Participants respond using a 7-point scale. The EIS has high internal consistency, and has been validated extensively (Pinel et al., 2014).

Inventory of Interpersonal Problems-32 (IIP-32; Horowitz, Alden, Wiggins, & Pincus, 2000). To assess interpersonal problems, participants will complete the 32-item circumplex version of the IIP. This widely used instrument reflects interpersonal inhibitions and excesses, with each item rated on a 5-point scale. Higher total scores indicate more interpersonal problems. The IIP-32 also has 8 subscales (Domineering, Vindictive, Intrusive, Cold, Socially Inhibited, Nonassertive, Overly Accommodating, and Self-Sacrificing) that comprise a circumplex of problematic interpersonal behavior around the main interpersonal dimensions of affiliation and control. Like the original measure (Horowitz, Rosenberg, Baer, Ureno, & Villansenor, 1988), the IIP-32 has evidenced good psychometric properties.

(3) RA-administered diagnostic assessment (baseline and posttreatment):

M.I.N.I. 7.0.2 International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al.,

2016). The M.I.N.I. is a brief, structured diagnostic interview for DSM-5 and International Classification of Diseases (ICD; World Health Organization, 2008) psychiatric disorder classification. With its administration time of approximately 15 minutes, the M.I.N.I. is the psychiatric interview of choice in clinical trials and epidemiological studies. Despite its brevity, its psychometric properties compare favorably to longer instruments like the *Structured Clinical Interview for DSM* (SCID; First, Spitzer, Gibbon, & Williams, 1996). As part of the diagnostic evaluation, the RAs will complete the *Clinical Global Impression* (CGI), a widely used observer-rated scale that includes a 0-7 judgment of illness severity for which higher scores indicate more extreme illness.

(4) Patient phase 2 during-treatment measures:

TOP-CS, SCL-10, EIS, IIP-32. All described previously.

Working Alliance Inventory-Short Form, patient version (WAI-SF-P; Tracey, & Kokotovic, 1989). The WAI is the most widely used alliance measure, assessing patient-therapist agreement on the goals and tasks of treatment, and the quality of their relational bond. This 12-item short form, assessing these dimensions from the patient's perspective, has demonstrated sound psychometric properties.

Credibility/Expectancy Scale, patient version (CEQ; Devilly & Borkovec, 2000). The CEQ is the most widely used and psychometrically sound measure of the patient's perceived logicalness of a given treatment and expectation for the personal efficacy of that treatment.

(5) Therapist phase 2 during-treatment measures:

Working Alliance Inventory-Short Form, therapist version (WAI-SF-T; Tracey & Kokotovic, 1989). This is the parallel version of the WAI-SF described above, though now as rated from the therapist's perspective.

Credibility/Expectancy Scale, therapist version (CEQ; Devilly & Borkovec, 2000). This is the parallel version of the CEQ described above, though now as rated from the therapist's perspective (i.e., the therapist's sense of how logical the patient sees the treatment and how optimistic the patient is about receiving benefit from it).

(6) Patient phase 2 posttreatment measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

TOP-Satisfaction with the Treatment Process (TOP-STP; Kraus et al., 2005). This 32-item measure assesses patient's satisfaction with their provider, the treatment they received, and the treatment milieu (e.g., staff, other patients, etc.).

(7) Therapist phase 2 posttreatment measure:

Nature of Termination Form (NTF). This measure was developed by the research team to assess the nature of patients' termination from the provider's open-ended perspective, as well as through a choice format of unilateral/patient-generated, unilateral/therapist-generated, or mutual. Therapists can also describe in an open-ended format any unusual or noteworthy circumstances that may have led to the termination of therapy with this client (e.g., transfer of client to another therapist).

(8) Patient phase 2 subsample follow-up measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

(9) Stakeholder exit interview protocols (patient and therapist versions)

(10) Patient phase 2 debriefing form

(11) Therapist phase 1 and 2 debriefing form

b. State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

For the baseline patient assessment during phase 2, RAs will administer via telephone the M.I.N.I., which will be audio-recorded. This will allow a different RA to review the recording and to make independent diagnostic and symptom severity determinations. With these two sets of ratings, we can then calculate interrater reliability on baseline diagnosis.

Audio recordings from the baseline diagnostic assessments will be digitally stored through the secure web-conferencing service. All data will be encrypted and password protected. Only the necessary research team members will know the login and password information and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings. The RAs, of course, will have completed the mandatory ethics training in human subjects' research, data management, and HIPAA compliance. These RAs will be independent evaluators who will not have access to other therapist or patient data. The recordings themselves will not be labeled with any identifiable information. The PI will routinely monitor the collection and analysis of recorded data.

After the recordings have been assessed for diagnostic reliability, the files will be securely deleted by the sponsored project contract term date of 7/14/20. No audio data or identifiable text data stemming from the recordings will be presented at

meetings or in published articles. Only the reliability coefficients will be disseminated with the results of the full trial.

c. State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #11 (Attachments).
Although the protocol does not involve deception, it does involve incomplete disclosure in Phase 2 given that participants are not given all of the information about the study until debriefing. Thus, in the debriefing form, we now provide participants the opportunity to withdraw their data upon learning the full scope of the research.

3. Background

a. Describe past findings leading to the formulation of the study.
Research has consistently identified significant variability in skill and outcomes between therapists (Baldwin & Imel, 2013; Boswell et al., 2013; Westra, Constantino, Arkowitz, & Dozois, 2011), even when therapists utilize an empirically supported treatment (EST). In fact, differences between treatment providers account for a greater portion of treatment outcome variance than the specific interventions delivered in controlled trials (Krause, Lutz, & Saunders, 2007; Wampold & Imel, 2015). Thus, improvements in MHC can occur by identifying effective providers in addition to promoting ESTs (Kraus et al., 2007).

In the largest study to date on this topic, our team investigated therapists' naturalistic treatment outcomes over many different problem domains (e.g., depression, anxiety, substance use, mania, sleep) in a sample of 6,960 patients and nearly 700 providers (Kraus, Castonguay, Boswell, Nordberg, & Hayes, 2011). The majority of therapists demonstrated a differential pattern of effectiveness depending on the problem domain, and therapist domain-specific effectiveness correlated poorly across domains suggesting that therapist competencies may be domain-specific, rather than reflecting a core attribute or general underlying therapeutic skill. Importantly, although some therapists demonstrated effectiveness over multiple problem domains, no therapists demonstrated reliable effectiveness across all domains. Further, a small, but notable 4% of the therapists did not demonstrate effective outcomes on any domain. These data suggest that in any population of therapists (payer network, hospital, or community mental health system), there is an opportunity for behavioral health to do what medicine did decades ago – encourage provider specialization. Virtually every clinician has an area where they are above average (82-96%; Kraus et al., 2011, 2016), and our research suggests that if they specialize to their unique skills, population-level outcomes (i.e., symptom reduction, behavior change, increased functionality) will improve dramatically. This would reflect a major, and likely highly impactful shift to current MHC systems.

However, patients and referrers are typically unaware of the unique track record ("report cards") of local-area providers, which represents a critical gap in knowledge transfer within the MHC system. Without systematically collecting and disseminating performance report cards, stakeholders (e.g., patients, therapists, administrators responsible for case assignment, primary care physicians) lack vital information on which to base MHC choices and referral decisions, and that can inform personalized treatment (Boswell, Constantino, Kraus, Bugatti, & Oswald, 2015). Conversely, there is potentially immense advantage to matching patients to providers based on scientific outcome data (Constantino, Boswell, Bernecker, & Castonguay, 2013).

Consistent with this notion, the Institute of Medicine (IOM) has made recommendations to: (a) customize care based on the patient's needs, (b) share knowledge, (c) engage in data-driven decision-making, (d) promote transparency (including information on performance and patient satisfaction; Kohn, Saxena, Levav, & Saraceno, 2004), and (e) use valid and reliable assessment instruments to assess progress and to aid decision-making. The IOM has also recommended that MHC patients be provided with information on the quality of practitioner care (e.g., provider report cards) and use this information when making treatment decisions. Importantly, we have survey data that point to MHC patients, therapists, and administrators endorsing such applied knowledge transfer as a high priority (Boswell et al., 2015). Provider track record report cards are meaningful data to the MHC patient population, as are the mental health benefits that could stem from being well matched to provider.

We have developed over the past 20 years an innovative, technology-based mechanism/intervention to deliver report cards and drive this match concept within a patient-centered MHC model (Kraus et al., 2011). Our longitudinal data suggest that our match algorithm, based on our multidimensional outcome tool (the TOP) is efficacious for MHC outcomes. In addition to our study highlighted above (Kraus et al., 2011), a more recent prospective study of 59 therapists and 3,540 patients resulted in a between-treatment controlled Cohen's d effect size of .80 (Kraus et al., 2016). Each therapist's first 30 patients were used to classify a therapist's skills in the 12 domains of symptoms and functioning as either statistically above average, average, or below average. The best matching algorithm functioned as follows: for each new, successive patient, he or she was classified as well-matched if the risk of harm was eliminated (i.e., the therapist was not below average when treating any elevated domain) and the therapist was above average in treating the patient's three most out-of-the-norm domains (e.g., depression, suicidality, and panic). Poorly matched patients had below average outcomes, with small effect sizes (d = .30) Well-matched patients, by contrast, achieved very large pre- vs. posttreatment effect sizes of d = 1.19. These data lend strong support that the proposed comparative effective research (CER) will yield similar results (i.e., increased efficacy and reduced harm) in realigning the skills of a large population of therapists in one of the forerunner Accountable Care Organizations (our partner Atrius) when

matching empirically derived therapist skills with patient need. The technology/intervention is well established, it has demonstrated efficacy, and awaits investigation in a well-powered randomized controlled trial (RCT).

4. Subject Population

a. State how many subjects you propose to use and state the rationale for the proposed number.

For the primary 3-level hierarchical model assessing treatment condition effects at the patient level on linear change rates within patients, we used Raudenbush and Liu's (2001) formula as incorporated in the Optimal Design program to determine the minimum numbers of therapists and patients needed to detect a moderate effect of condition (standardized difference between change rates = .50). With a minimum of 6 measurements spaced over the maximum 16 treatment weeks and assuming 5 patients per therapist, an intra-class correlation of .15, and an alpha of .05, we will need a total of 44 therapists and 220 patients to achieve a power of .80 to detect moderate condition effects on linear change rates. Factoring a 20% dropout rate at the patient level, running our experiment on 264 patients (6 per therapist) should provide sufficient statistical power to detect group differences on our primary outcome variables. To summarize, based on this power analysis, we will recruit 44 therapists (tracking the routinely administered outcomes for 15 of their patients each) for phase 1 (total phase 1 patient n = 660). We will then recruit 264 patients for the phase 2 trial, assigning patients to the same 44 therapists who participated in phase 1 (they will see 6 cases each during the trial).

b. Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, professors, subjects with learning disabilities, mental health disorders, etc.). Please incorporate specific inclusion/exclusion criteria (e.g. physical and psychological health, demographic information, or other unique characteristics).

Therapist participants: As noted, our target sample is 44 therapist participants. Reflecting Atrius Health's psychotherapist demographics, we anticipate that our sample will roughly breakdown as follows: 64% social workers and 36% psychologists. Demographically, the mean age of therapists is 54 years (range = 28-72). The majority of the eligible sample is female (61.5%) and White (92.8%; 6% Hispanic). Based on these projections and our power analysis, our targeted/planned therapist enrollment is indicated in an attached Targeted/Planned Enrollment Table (Therapists).

Patient participants: Patient participants will be adult men and women (age 18-65) largely referred by Atrius primary care and obstetrics/gynecology for triage and treatment through Atrius' behavioral health specialty practice. All patient participants, including those self-referred, will have an Atrius primary care physician (PCP). Recruitment to the study simply means a willingness to be randomized to

condition and to complete a few study-specific measures. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the network will be eligible. Atrius has implemented a care-model for mental health to support PCPs working with patients who have the most pressing behavioral health issues. Therefore, it is most likely that the sample will be predominated by the following diagnoses: complex mood, trauma, and anxiety disorders, eating disorders, simple schizophrenia, borderline personality disorder, substance abuse, and insomnia.

The composition of our patient sample will roughly match the average Atrius utilization data for age, gender, race, and ethnicity. We expect the average age to be 40 years (SD = 18.79 years). We expect that 62% will be female (38% male). For race/ethnicity, based on recent Atrius outpatient data, we expect the following: 76% White, 10% Black/African American, 5% Asian, 4.5% multiracial, 4.5% Hispanic, and less than 1% Native American and Hawaiian/Pacific Islander. These figures are consistent with county census data in the greater Boston area (including North and South Shores). The only exclusion criteria will be patients who are not the primary, informed decision-maker for their care and adults over age 65 years. The latter is because older adults (a) represent a small portion of patients at Atrius, and (b) their mental health treatment is complicated by aging issues for which specialized care may be required. Based on these projections and our power analysis, our targeted/planned therapist enrollment is attached in an Estimated Final Racial/Ethnic and Gender Enrollment Table.

c. State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.

We are not specifically targeting these specific vulnerable populations, and our design and/or the Atrius system will specifically exclude minors and prisoners. However, given the effectiveness design focused on maximizing ecological validity, some of our patients are sure to have economic and educational vulnerabilities, which are risk factors for mental health issues. Some women might also be pregnant.

d. If women, minorities, or minors are not included, a clear compelling rationale must be provided.

Minors will be excluded because they are typically not solely responsible for their own treatment decisions, and the outcome measure used in this study, and on which the match manipulation is based, focuses on adults.

e. State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.

N/A

f. State the number, if any, of subjects who are involved in research conducted abroad and describe any unique cultural, economic or political conditions.
N/A

g. Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach advertisements, flyers, etc. in Section #11 (Attachments). Note: Potential subjects may not be contacted before IRB approval.
Therapist participants:

Recruitment will be coordinated among our UMass-employed PC, clinic staff members, and clinic administrators, and will involve presenting information about the study (both phases 1 and 2) to providers through flyers, verbal script, or email. Interested therapist participants will meet or speak via teleconference with the PC to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed (this all occurs prior to the baseline period for establishing TOP "report cards" that will inform the match in phase 2). Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the study-specific assessments in which their study patients will engage in both phase 1 and phase 2 (though they will not have access to these research data at any time). Therapists will also need to consent to completing a few study-specific measures at phase 1 baseline and throughout treatment with each patient during the phase 2 RCT (these are described below in the listing of relevant phase 2 attachments to this protocol). For phase 1, therapists will be compensated with a $20 Amazon gift card for a one-time completion of the phase 1 baseline forms. For phase 2, they will be compensated $50 per patient (again in the form of Amazon gift cards) for completing several measures of therapy process at multiple points throughout each patient's treatment.

Patient participants:

Phase 1 - During phase 1, patients will only be engaged in the study by virtue of registering into the TOP system at their treatment baseline, and completing the TOP at baseline, week 8, and their termination point or week 16, whichever comes sooner (to mimic the definition of treatment outcome in the RCT phase discussed below). Given their involvement in this one element of the research protocol, patients will need to give the staff at their clinic verbal consent to be contacted by the PC or an RA. The staff members will collaborate with the research team to track these patients being treated by a study-consenting therapist during this phase 1 part

of the study. Once contacted via telephone, the PC or RA will explain the nature of the patient's involvement, which will simply involve registering on the TOP system, and completing the TOP main outcome measures at baseline, week 8, and termination. The patient will then be directed to a secure online system to complete their consent form and their baseline TOP forms. For the week 8 and the posttreatment TOP administrations, the PC will send specific links that will direct patients to the measure. The online system was developed and is maintained by our subcontractor, ORI. For this minimal time burden, patients will be entered into a raffle to win one of ten $25 Amazon gift cards. These 660 patients will be involved in phase 1 only. Thus, they will be debriefed by the PC or RA after they terminate their treatment-as-usual.

Phase 2 - Once referred into the Atrius behavioral health system per usual care process, the front desk staff at the participating clinics will ask potential patient subjects if they are interested in hearing more about the study were they to be treated within Atrius with individual outpatient psychotherapy (versus being referred out or receiving care that does not involve individual outpatient psychotherapy). Next, a triage clinician at the clinics will determine that patients make their own treatment decisions and will receive individual therapy as part of their "in-house" treatment plan; if so, the patient is study-eligible. Atrius clinic/triage staff will provide the research team with a daily list of referrals (via direct telephone contact or through a secure server) of patients who have provided verbal consent to be contacted about the study and who have been determined to be appropriate for relevant treatment within the Atrius system. The PC will then reach out to patients who provided verbal consent to be contacted.

If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a telephone diagnostic interview with a trained graduate clinical psychology RA (employed at either UMass or University at Albany). The RA will first review the study details/procedures and obtain consent through an online baseline survey to which the patient will be directed. Patients will be informed that their participation in the trial will largely mimic the same treatment that they would receive if they were not participating. All patients will also be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience. Patients will be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they do request a transfer earlier, this will be treated as a dropout point for the sake of the trial (i.e., their data will not be analyzed in the primary analyses). Patients will also be informed that they will complete all assessments that are part of their routine clinical care, as well as several study-specific measures, for which they will be compensated $50 total.

h. Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.
Therapist participants:

Therapists will complete a few study-specific measures at phase 1 baseline for which they will be compensated $20 in total (in the form of an Amazon gift card).

During Phase 2, therapists will also complete a few study-specific measures throughout treatment with each of the 6 patients seen during the phase 2 RCT; they will be compensated $50 per patient for this additional, but minimal, time burden. The compensation will again be in the form of Amazon gift cards.

If therapists complete their measurement schedule through all possible contact points for a given participating patient (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination for a participating patient that occurs prior to week 16 of treatment, they will receive full compensation (i.e., a $50 gift card for that patient). However, if a therapist withdraws from the study, they will have the option to be compensated on a prorated basis for the measures that they have already completed regarding each of their participating patients. This proration works out to approximately $3 per week for a participating patient, which will be deducted for the number of weeks "missing" from therapists' assessment schedule (i.e., based on the point at which the therapist withdrew from the study). For example, if a therapist completes the measurement schedule for a given patient through week 8 (9 weeks, including baseline) and then withdraws from the study, they will have "missed" 8 weeks of data collection for that participating patient. Their compensation for this participating patient will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26. This adjustment will be completed for any and all relevant participating patients. To summarize, therapists who withdraw from the study will have the option either to (a) receive their relevant prorated compensation, or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

Patient participants:

Patients in phase 1 will register into the TOP system at their treatment baseline and complete the TOP at baseline, week 8, and their termination point or week 16, whichever comes sooner. For this minimal time burden, patients will be entered into a raffle to win one of ten $25 Amazon gift cards. These 660 patients will be involved in phase 1 only. Provided that patients complete the baseline assessment, they will be entered into the raffle. And given the small amount of compensation and the low odds of winning the raffle, they will also remain in the raffle even if their treatment ends prior to the second assessment point (week 8), and even if they decide not to complete the treatment termination assessment. Patients will be withdrawn from

the raffle if they withdraw from the study protocol (thereby withdrawing their data and indicating that they no longer wish to be contacted by the research team).

Patients in Phase 2 will undergo a semi-structured diagnostic interview at both baseline and posttreatment, as well as complete several study specific measures throughout treatment (and, if randomly selected, at a follow up); they will be compensated $50 total for these non-routine aspects of their care. The compensation will be in the form of an Amazon gift card. If patients complete their measurement schedule through all possible contact points (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination that occurs prior to week 16 of treatment, they will receive full compensation. However, if they drop out of treatment prior to week 16, and their end point was not a planned termination that can be considered posttreatment for the purpose of the study, compensation will occur on a prorated schedule. This works out to approximately $3 per week, which will be deducted for the number of weeks "missing" from the schedule. For example, if a patient completes the measurement schedule through week 8 (9 weeks, including baseline), and they did not engage in a planned termination, they will have "missed" 8 weeks of data collection. Their compensation will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26.

Patients who withdraw from the study (which is distinct from simply dropping out of treatment) will be given the option to (a) receive prorated compensation for the completion of measures up until the point of withdrawal (following the proration schedule outline above), or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the patient participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Finally, note that in the event that a participant (either a patient or therapist) withdraws from the study during phase 2, the other dyad member (either the patients seen by a withdrawing therapist or the therapist treating a withdrawing patient) will not be penalized; that is, as long as they have already consented to the study, they will receive the full amount of reimbursement (i.e., a $50 gift card) regardless of the point at which their patient/therapist withdraws. However, note that consistent with the wishes of the participant, we will, of course, stop collecting data at the point of withdrawal (i.e., if therapists withdraw, we will stop collecting data from their patients who will be compensated fully; if patients withdraw, we will stop collecting data from their therapist regarding that patient and the therapist will be compensated fully for that patient).

i. **Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How**

much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be 1-session for a total of 90 minutes).
A) The project is funded in the form a cost-reimbursement contract for which a specific milestone schedule exists. The contract start date is 9/15/16 and the contract term date is 7/14/20. All analyses will be completed by the term date. Details are available in the attached milestone schedule.

B) Therapist subjects will be involved for 6 months in phase 1, as well as through the phase 2 trial (approximately 2 years, though with variability depending on when they have been assigned and have treated their 6 study cases). Patient subjects in phase 1 only will be involved in the study protocol through their actual termination point or 16 weeks, whichever comes sooner. Patients in phase 2 only will be involved in the study protocol through their actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after termination on a randomly-selected subsample of 40 patients).

5. Risks

HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." This also includes risks to subject confidentiality and any discomforts, hazards, or inconveniences.

For the categories below, include a description of risks.

a. Describe the risks related to:
Physical well-being
None anticipated.

Psychological well-being
Regardless of condition, all participating clinics will employ their usual triage assessments, therapists will employ their usual treatments, and patients will be receiving their usual treatments. Consequently, there are no risks from our research protocol over and above what would normally be expected in routine assessment and psychotherapy, and the clinics all have their clinical and safety protocols in place (and clinical personnel to execute them).

In treatment, some individuals may experience emotional upset during sessions. Additionally, some participants may experience disappointment with their rate of progress or setbacks. The risk associated with such reactions will be addressed clinically by the therapists who are treating these issues and who have peer and administrative support. To reiterate, these treatment risks would occur in the course of treatment-as-usual. These are not additional risks stemming from the research

protocol. Further, outcome monitoring systems, which the basis of our protocol, are already being used by Atrius providers without incident.

As is typical in psychological research, some of the assessment questions from the research measures may be experienced as intrusive and/or may cause anxiety. The risk from such increased anxiety, however, is minimized by the use of skilled and extensively trained assessors who are aware that such reactions may be related to a person's presenting problems, or simply a function of the intimate and emotionally intense nature of psychological services. In addition, the PIs, PC, and Atrius site staff and administrators will be available to meet with any participant who may be unduly disturbed due to the few research tasks. Because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and current address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

There is also the possibility that the research team will become aware of critical items being endorsed on the TOP (e.g., suicidal ideation). In this case, the PI or PC (who will be responsible for regularly reviewing TOP data as it is collected) will inform the Atrius Co-PI (Dr. Nordberg), who will determine if the therapist should be notified of these critical item responses. However, as Atrius therapists will constantly be engaging in psychological and risk assessments as part of routine care, this information will likely be known already. To be sure, though, Atrius will have a protocol in place to share critical item data without having to share the full TOP report (which, as per the research design, is not being shared with clinicians).

Economic well-being

Given that therapist performance data are being collected, it is reasonable to be concerned about possible employment implications were an employer (i.e., clinic administrator) to attempt to interpret study information incompletely (i.e., infer lack of therapist effectiveness to the point of questioning employability). This risk, however, is extremely minimal for the following reasons:

(1) As a condition of being involved in the study, clinic administrators will be required to agree that therapists' participation or non-participation in this research will in no way affect their standing/employment at their community mental health clinic.

(2) The research team will not reveal therapist performance data to clinic administrators or staff members; that is, the study could be considered "triple-

blind." Neither patients nor therapists will know when they are in an experimentally-matched vs. typically-matched dyad, and administrators/staff members will not have access to the therapists' report cards.

(3) However, administrators and staff members are required to be in the know about well-matched therapist "short-lists," as this is essential to the research design; that is, when patients are randomized to a well-matched therapist, those potential therapists need to be identifiable. It is possible that administrators or staff members might misinterpret these data to suggest that a given therapist is ineffective (if he or she is never or rarely showing up on a shortlist). However, we will guard against this misinterpretation by educating administrators and staff members that the shortlist only represents, in a small cross-section of time, therapists that have been shown to be effective on at least 1 of 14 domains, which represents a given patient's most severe problem at that time (the match criterion). We will stress that this does not mean that a therapist is globally ineffective. It may just be that patients randomly assigned to the match group are tending not to have the types of problems for which a given therapist is relatively effective. That therapist, though, could be highly effective at treating one or even many other domains.

(4) Finally, administrators and staff members will not be told which therapists are or are not participating in the study. Thus, lack of being on a shortlist, for all that they will know (unless a therapist openly reveals that he or she is participating in the study), could simply connote a choice to not participate in the project.

Social well-being
None anticipated.

Breach of confidentiality (including audio/video taping)
A breach of confidentiality represents a risk, but every step will be taken to minimize this risk. Atrius clinics and ORI routinely handle private health information and are in compliance with HIPAA regulations. Any "hard" materials (e.g., diagnostic assessment summaries) that are collected will be stored in a locked cabinet in the PI's Psychotherapy Research Lab. There will be no hard copy data collected at the Atrius clinic sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. In addition, digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted.

b. For research conducted internationally, describe any political or sociocultural considerations that may affect your research design (for example, in some communities it may not be customary to sign documents, etc.)
N/A

c. Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.

The Co-PIs, project coordinator, Atrius site staff members, and Atrius administrators will monitor the treatments and data collection; thus, they can assist in regularly monitoring any adverse events. Such negative occurrences are unlikely to be trial-related, as all patients will be receiving treatment-as-usual. Therefore, any adverse event will be addressed with the Atrius clinics well-established procedures for monitoring services and managing treatment-related disturbances. Nevertheless, any adverse event will be recorded and immediately reported to the IRB (UMass), PCORI (funder), and the project's Data Safety and Monitoring Board (DSMB).

Should, during the course of the study, a patient show evidence of psychological or physical deterioration, the patient will be assessed comprehensively in the domains of concern (except in the case of a life-threatening physical emergency, such as the emergence of acute chest pain, in which case 9-1-1 will be called immediately). If the therapist deems that the patient meets criteria for a psychiatric hold (e.g., patient is an imminent danger to self or others), the therapist will arrange for the patient to be brought to the emergency department and will contact his/her Atrius administrator and the PI to debrief. If a patient is not meeting criteria for a psychiatric hold, but is showing clear signs of decreased mental status, the therapist will continue to meet with the patient, as well as – in consultation with the Atrius administrator – make arrangements for the most appropriate level of care (e.g., day treatment).

As noted, because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and current address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

Also as noted, there is also the possibility that the research team will become aware of critical items being endorsed on the TOP (e.g., suicidal ideation). In this case, the PI or PC (who will be responsible for regularly reviewing TOP data as it is collected) will inform the Atrius Co-PI (Dr. Nordberg), who will determine if the therapist should be notified of these critical item responses. However, as Atrius therapists will constantly be engaging in psychological and risk assessments as part of routine care, this information will likely be known already. To be sure, though, Atrius will have a protocol in place to share critical item data without having to share the full TOP report (which, as per the research design, is not being shared with clinicians).

6. Benefits

a. Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).

The most direct benefit a participant in this study may receive is the reduction of symptom-related distress and improved functioning. In addition, patients (especially those in the match condition) will receive more personalized MHC. Psychotherapists (especially those in the match condition) may experience a greater level of positive impact across their caseloads. Given that the actual treatments being provided will not be manipulated, the benefits of participation are judged to far outweigh the potential study-specific risks.

There is immense potential for future therapists and patients to benefit from the results of this study; if the hypotheses are supported, there will be cause for substantial revamping of MHC systems to capitalize on matching patients to therapists who have an empirically demonstrable track record of strength in treating patients with similar presenting problems.

7. Procedures to Maintain Confidentiality

a. Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.

Multiple steps will be taken to protect confidentiality. As mentioned, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy data collected at the Atrius clinic sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. In addition, digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted.

Only designated study personnel will have access to identifiable, study specific, private information about human subjects. When registering on the TOP system, both patients and therapists are assigned a random number code that links all subsequent assessments and is separated from identifiable information. This random number code will function as each participant's study code and will be used to link participants' data. As noted, all therapist and patient data (outside of diagnostic assessment summaries) will be collected through a web-based platform. The assigned participant code will be used to link/aggregate information, so private information will not be requested after the baseline assessment/consent process. Only the PI and essential research staff will have access to the list that links

identifiable information with the participant's study code. Any audio recordings will be encrypted and password protected. Only the Co-PIs will know this password and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings; however, they will not have access to additional identifiable information (only the information required to complete the analysis). For any data used for research and publication purposes, the confidentiality of participant information will be ensured.

b. If information derived from the study will be provided to a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

The PI is required to submit information (i.e., contractual "deliverables") on a regular basis to PCORI (the study sponsor), including IRB protocols, interim progress reports, advisory board meeting minutes, engagement plan updates, evidence of diagnostic criterion reliability from training cases, interim data reports, presentation abstracts and documentation of acceptance, manuscript copies, letters of endorsement from scientific and consumer groups, final data analysis summary, and final research report. Details on deliverables are available in the aforementioned (and attached) milestone schedule. No protected health information will be transmitted to PCORI.

c. Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.

As noted, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy data collected at the Atrius clinic sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. Digital recordings of diagnostic assessments will be stored in password protected website, and securely deleted by the project contract's term date. Only the relevant members of the research team will have access to the participants' data and only the PI will have long-term access to identifiable information. As noted, all assessments will be linked with a de-identified participant code. Any records linking the code to the participant's name or voice recording will be kept in a separate locked file cabinet in the PI's office. These records will be destroyed 5 years after the contract term date.

8. Potential Conflict of Interest

a. Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)? Y

b. **Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?** N

c. **Is any Investigator(s) a member of an advisory board with the Sponsoring company?** N

d. **Do any investigators receive gift funds from the Sponsoring company?** N

e. **Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?** Y

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner. If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. If you answer yes to any of the questions above, please go to the policies for more information.

9. Informed Consent

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below, for each Consent Form(s), Alteration Form(s), and Waiver(s).

9.1. Consent Form – therapist phase 1 & 2 consent forms

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
PC or an RA.

How is consent being obtained?
Therapists will meet or speak via teleconference with the PC or an RA to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
The PI and his collaborators will provide close oversight of the entire protocol.

9.2. Consent Form – patient phase 1 consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
Atrius clinic staff will obtain verbal consent from patients about their willingness to be contacted about the study. Patients will then meet or speak via teleconference with the PC or an RA to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed (this is the case for both phase 1 and phase 2).

How is consent being obtained?
If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a telephone diagnostic interview with a trained graduate clinical psychology RA (employed at either UMass or University at Albany). The RAs will first review the study details/procedures and obtain consent through an online baseline survey to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will be an inclusion criterion for the study. Moreover, if a clinic staff member, the PC, or an RA interacts with a therapist or patient who appears to have competency issues in the decision-making process for engaging in the study, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the study. The DSMB will be consulted if appropriate.

9.3. Consent Form – patient phase 2 consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
Atrius clinic staff will obtain verbal consent from patients about their willingness to be contacted about the study. Patients will then meet or speak via teleconference with the project coordinator or a research assistant to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed (this is the case for both phase 1 and phase 2).

How is consent being obtained?
If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a telephone diagnostic interview with a trained graduate clinical psychology RA (employed at either UMass or University at Albany). The RAs will first review the study details/procedures and obtain consent through an online baseline survey to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will be an inclusion criterion for the study. Moreover, if a clinic staff member, the PC, or an RA interacts with a therapist or patient who appears to have competency issues in the decision-making process for engaging in the study, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the study. The DSMB will be consulted if appropriate.

9.4. Consent Form – patient exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a patient agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will have been an inclusion criterion for the main study. Moreover, if the interviewer interacts with a patient who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the interview protocol. The DSMB will be consulted if appropriate.

9.5. Consent Form – therapist exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a therapist agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the therapist will be directed. Coercion will be minimized by clearly stating that participation is voluntary.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

If the interviewer interacts with a therapist who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the interview protocol.

10. Assent Background

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

11. Attachments

Document Type	Document Name	Attached Date
Questionnaires	Patient Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	Therapist Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	TOP-STP	10/04/2016
Questionnaires	PCORI_Nature of Termination Form	10/04/2016
Questionnaires	Stakeholder Exit Interview Protocols	10/04/2016
Other	PCORI Milestone Schedule	10/04/2016
Other	PCORI_Targeted Enrollment Tables	10/04/2016
Other	Participant Flow	10/04/2016
Other	Data Collection Schedule	10/04/2016
Federal Grant/Sub-contract	PCORI IHS-1503-28573_Constantino_executed contract	10/04/2016
Federal Grant/Sub-contract	PCORI_IHS_Research Plan_final update 9-12-16	10/04/2016
Federal Grant/Sub-contract	PCORI Original Contract Proposal_all sections	10/04/2016
Other	PCORI_Phase 1_Patient Debriefing Form	10/04/2016
Other	Constantino Lab Personnel Link- Google Docs	10/04/2016
Advertisements	PCORI_Phase 1_Clinician Recruitment_All Forms	11/13/2016

	Combined_R1	
Advertisements	PCORI_Phase 1_Patient Recruitment_Verbal Script_R1	11/13/2016
Advertisements	PCORI_Phase 2_Patient Recruitment_Verbal Script_R1	11/13/2016
Other	PCORI_Phase 1 & 2_Therapist Debriefing Form	11/13/2016
Other	PCORI_Phase 2_Patient Debriefing Form_R1	11/13/2016
Other	PCORI_Phase 2_Patient Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Patient Data Collection Reminder Call Script	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Reminder Call Script	11/13/2016
Other	PCORI_Phase 1_Patient Data Collection Email Template	11/13/2016
Other	PCORI_Phase 1_Patient Data Collection Reminder Call Script	11/13/2016
Other	PCORI_Phase 1_Therapist Data Collection Email Template	11/13/2016
Other	PCORI_Phase 1_Therapist Data Collection Reminder Call Script	11/13/2016
Questionnaires	CGI	11/13/2016
Questionnaires	MINI 7.0.2 Standard	11/13/2016
Questionnaires	Patient Phase 1 Consent & Baseline Measures Packet_R1	11/13/2016
Questionnaires	Patient Phase 2 Consent & Baseline Measures Packet_R1	11/13/2016
Questionnaires	Therapist Consent & Baseline Measures Packet_R1	11/13/2016

Obligations

Obligations of the Principal Investigator are: Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes; Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded; Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days; Continuing Review – IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.” Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events/Unanticipated Problems - All events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than five (5) working days; Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.”

The Principal Investigator has read and agrees to abide by the above obligations. Y

B. Summary of the 1st formal modification to the PCORI contract (July 2017), and the full revised study protocol (1st revision) submitted to, and approved by, the University of Massachusetts Amherst Institutional Review Board (November 2017)

CONTRACT MODIFICATION SUMMARY

On July 10, 2017, PCORI approved the 1st contract modification (IHS-1503-28573 Modification 001), which included the following changes:

- Effective June 7, 2017, Atrius Health was removed as our clinical partner and subcontract site, and Dr. Samuel Nordberg was removed as site Co-PI.

- Effective August 1, 2017, Psychological and Behavioral Consultants (PsycBC) was added as our clinical partner and subcontract site, and Don Sykes was added as site Co-PI.

- The project's milestone schedule was revised in light of the subcontract site change.

In concert with this modification, we submitted the following 1st revision of our study protocol to the UMass IRB, which was approved in November 2017. As outlined in the revised protocol, the *major* changes included:

- Phase 1 of trial no longer required recruiting and consenting a subsample of patients. Rather, because PsycBC already routinely used our multidimensional outcome tool (the TOP) to track patient improvement, we had de-facto baseline data on therapists' historical strengths and weaknesses (across a minimum of 15 cases) in treating the 12 mental health domains that the TOP assesses and on which our match algorithm is based. Thus, Phase I now simply involved recruiting and consenting therapists to the study for whom we already possessed (or would soon possess based on standard operating procedures) the requisite cases and performance data, which we could securely access via the previously executed business agreement between ORI and PsycBC.

- Phase 1 therapist recruitment procedures were adjusted to align with our new clinical partner's (PsycBC) communications with their providers and their daily operations.

- Phase 2 patient recruitment procedures were adjusted to align with PsycBC's recruitment flow and daily operations.

PROTOCOL
APPLICATION FORM
SOCIAL, BEHAVIORAL, AND EDUCATIONAL FULL BOARD
HUMAN SUBJECTS IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL RESEARCH

University of Massachusetts Amherst (UMass)
Institutional Review Board (IRB)

Protocol ID: 2016-3401
Title: Enhancing Mental Health Care

Revision Form
1. Summarize the proposed changes to the protocol in lay terms (including details of ALL changes proposed AND modify all relevant protocol sections and attachments accordingly).
As recently and extensively discussed with Margaret Burggren and Gaurav Dhawan, we submit here a revised protocol based on a contract modification for our PCORI-funded research project. The revisions are included in all relevant sections of this protocol; however, for ease of review, we have also attached a Word document that tracks all changes (in the "Other" section of the attachments page). The title of the document is: "PCORI IRB Proposal_R1_for PsycBC_FINAL submitted.docx"

PsycBC is our new clinical subcontractor (replacing Atrius Health). All revisions in the protocol itself, and in all attachment attachments, reflect this new partnership.

In the aforementioned Word document, we also note with comment bubbles when an attachment to this protocol has been revised, has stayed the same, or has been deleted because it is no longer relevant. Again, we hope that such use of tracked changes/comments is helpful to the review team. Of course, we can also answer any remaining questions.

Thank you for your time and efforts in reviewing this protocol revision.

2. Indicate Level of Risk involved with the changes proposed.
No change.

3. Describe any Other Changes.
None

Protocol Director: Michael J. Constantino
Degree: PhD
Title: Professor
Department Name: Psychological & Brain Sciences
Mailing Address: 612 Tobin Hall, 135 Hicks Way
Phone: 5-1388; **Fax:** 5-0996
E-mail: mconstantino@psych.umass.edu
Human Subjects Training Completed? yes

Subject Populations(s) Checklist	**Yes/No**

Minors (under 18)	N
Pregnant Women	N
Cognitively Impaired or Decisionally Challenged	N
Older individuals (75 and over)	N
Healthy Volunteers	N
Students/Employees	N
International Populations	N
Prisoners	N
Other (i.e., any population that is not specified above)	Y

Other: Subjects will include two mental health care stakeholder groups: (1) therapists affiliated with PsycBC who are providing outpatient psychotherapy, and (2) adult patients receiving psychotherapy for varied mental health complaints from the participating therapists. PsycBC, a formal subcontract to UMass on this project, is an innovative health care organization and one of the largest providers of outpatient mental healthcare services in Ohio. PsycBC's role on this project is restricted to providing the research team access to these two subject populations, and assisting the team in recruitment. Thus, PsycBC is not engaged in human subjects' research.

Study Location(s) Checklist	**Yes/No**
University of Massachusetts Amherst	Y
Baystate Medical	N
University Health Services	N
Hartford Hospital	N
Other (Specify other Study Locations)	Y

Other: All study operations will be coordinated through Dr. Michael Constantino's (PI) Psychotherapy Research Lab at UMass Amherst. Subject data will be collected through our clinical partner, PsycBC, which employs a large team of psychiatrists, advanced practice nurses, psychologists, clinical counselors, and social workers serving children, adolescents, adults, and families in locations throughout Ohio and northern Kentucky. PsycBC's experienced specialists provide therapy for a wide range of mental health issues. PsycBC includes multiple treatment sites in Ohio that will contribute to data collection.

General Checklist	**Yes/No**
Training Grant?	N
Funded Study (or proposal submitted to sponsor)?	Y
Cooperating Institution(s)?	Y
Federally Sponsored Project?	Y
Human blood, cells, tissues, or body fluids (tissues)?	N
Subjects will be paid for participations?	Y

Cooperating Institution(s): (1) University at Albany, SUNY (Dr. James Boswell; Co-PI and subcontract); (2) Outcome Referrals Institute, Inc. (ORI; Dr. David Kraus; Co-PI and subcontract); and (3) PsycBC (Dr. Tom Swales; subcontract director). Note: At the time of this revision, an IAA has already been established for the approved original protocol with SUNY Albany and ORI. After consulting with UMass IRB staff, it is now clear that our new subcontract, PsycBC, is not engaged in human subjects' research; thus, no IAA is required/requested.

Funding Checklist
Grants/Contracts:

Funding Administered By: UNIVERSITY
PGCA#: 1503-28753
GAID#:
Funded By: Patient-Centered Outcomes Research Institute
1828 L Street, NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700 | Fax: (202) 355-9558
info@pcori.org
Principle Investigator: Michael J. Constantino
Grant/Contract Title: Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths

Are the contents of this protocol the same as described in grant/contract proposal? Y
Is this a training grant? N
Are any subcontracts issues under this grant? Y

Fellowships – None
Gift Funding – None
Dept. Funding – None
Other Funding – None

1. Purpose of the study

a. Provide a brief lay summary of the purpose of the study.
Research has shown that mental health care (MHC) providers differ significantly in their ability to help patients. In addition, providers demonstrate different patterns of effectiveness across symptom and functioning domains. For example, some providers are reliably effective in treating numerous patients and problem domains, others are reliably effective in some domains (e.g., depression, substance abuse) yet appear to struggle in others (e.g., anxiety, social functioning), and some are reliably ineffective, or even harmful, across patients and domains. Knowledge of these provider differences is based largely on patient-reported outcomes collected in routine MHC settings.

Unfortunately, provider performance information is not systematically used to refer or assign a particular patient to a scientifically based best-matched provider. MHC systems continue to rely on random or purely pragmatic case assignment and referral, which significantly "waters down" the odds of a patient being assigned/referred to a high performing provider in the patient's area(s) of need, and increases the risk of being assigned/referred to a provider who may have a track record of ineffectiveness. This research aims to solve the existing non-patient-centered provider-matching problem.

Specifically, we aim to demonstrate the comparative effectiveness of a scientifically-based patient-provider match system compared to status quo pragmatic case assignment. We expect in the scientific match group significantly better treatment outcomes (e.g., symptoms, quality of life) and higher patient satisfaction with treatment. We also expect to demonstrate feasibility of implementing a scientific match process in a community MHC system and broad dissemination of the easily replicated scientific match technology in diverse health care settings. The importance of this work for patients cannot be understated. Far too many patients struggle to find the right provider, which unnecessarily prolongs suffering and promotes health care system inefficiency. A scientific match system based on routine outcome data uses patient-generated information to direct this patient to this provider in this setting. In addition, when based on multidimensional assessment, it allows a wide variety of patient-centered outcomes to be represented (e.g., symptom domains, functioning domains, quality of life).

b. What does the Investigator(s) hope to learn from the study?

The goal of this project is to test the effectiveness of an innovative, scientifically-informed patient-therapist referral match algorithm based on MHC provider outcome data. We will employ a randomized controlled trial (RCT) to compare the match algorithm with commonplace pragmatic referral matching (based on provider availability, convenience, or self-reported specialty). Psychosocial treatment will remain naturalistically administered by varied providers (e.g., psychologists, social workers) to patients with mental health concerns. We hypothesize that the scientific match group will outperform the pragmatic match group in decreasing patient symptoms and treatment dropout, and in promoting patient functional outcomes, perceived treatment credibility, outcome expectation, and care satisfaction, as well as therapeutic alliance quality. Doing so will establish the match algorithm as a mechanism of effective patient-centered MHC, and will suggest that this scientifically derived patient-provider matching intervention can be integrated into MHC systems to aid in treatment decision making, as well as increase personalization.

2. Study Procedures

a. Describe all study procedures.

We will compare the efficacy of naturalistic treatment either with or without the aid of scientific matching to a provider with a double-blind RCT. The project will involve two main phases. First, we will access a naturalistic baseline assessment of consenting PsycBC therapists' performance to determine their relative strengths and weaknesses in treating the problem domains measured by a multidimensional outcome tool. This period will establish our therapist sample pool and inform the RCT match manipulation (a match will represent a patient being assigned to a therapist who has empirically demonstrated during the baseline phase that he or she is stably effective at treating patients with the same type of presenting complaint).

Second, and after the baseline period, new consenting outpatients will be randomly assigned to the match (experimental) or no match (control) condition. The PsycBC administrators and their project-specific coordinator will collaborate with the research team to apply the randomization protocol. Treatment outcome will be assessed through the patient's actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after the point of termination on a randomly selected subsample). Outside of being matched to a therapist from a short-list of providers who have demonstrated (during the phase 1 baseline) reliable success in treating the patient's primary problem area, and completing study-specific measures for which participants will receive monetary compensation, treatment will be delivered as usual (the short list still allows for pragmatic considerations like availability and administrator assignment options).

Additional methodological details by study phase follow.

Phase 1: The most significant revision to the research protocol is that we no longer need to recruit/enroll patients for phase 1. Rather, phase 1 now focuses solely on PsycBC clinicians as our research participants. To inform the match condition, we will first establish the baseline track record of participating therapists' performance (across a minimum of 15 adult psychotherapy cases each) to determine their strengths in treating behavioral health domains measured by the primary outcome measure on which the match algorithm is based – the Treatment Outcome Package (TOP; Kraus, Seligman, & Jordan, 2005), which is described below in the listing of relevant phase 1 attachments to this protocol. Developed and processed by our Co-PI (Dr. Kraus) and his subcontractor company, Outcome Referrals, Inc. (ORI), the TO is administered routinely as a core element of the PsycBC care model. That is, PsycBC already has an executed business agreement with ORI to have their patients complete the TOP as part of their standard clinical routine. Thus, we can leverage the existing PsycBC infrastructure to support the present study with little to no extra burden on administrators, providers, and patients. Moreover, although patient data are part of this baseline phase, they are protected within the business agreement between ORI and PsycBC, and the agreement allows for these coded data to be used to establish therapists' performance "report cards." So, to reiterate, patient TOP

data are collected as part of standard operating procedure for PsycBC. At this stage, we are not collecting these patient data as a research protocol; rather, these coded patient data points (i.e., clinical care data points) inform our match intervention (by establishing therapist performance report cards across at least 15 cases) that is at the heart of phase 2 (described below). In phase 1, we are only actively recruiting provider participants; thus, no patient protected health information (PHI) is transmitted to the research team.

Importantly, at the time of this proposed IRB revision, most PsycBC clinicians who will choose to participate in the study will already have baseline data on the minimum 15 adult cases (through the patient's actual termination point or 16 weeks, whichever comes sooner) to establish their track record. In these cases, we simply need to enroll the therapist in the study (as discussed next). For therapists who wish to participate, but have yet to accumulate baseline performance data on the minimum 15 cases, we will track their performance (as per the TOP) on new, consecutive referrals until 15 total cases have been established for which the patient has either terminated or has been seen for at least 16 weeks. Few therapists will fall in this second category, and even if they do, they will generally only need a few cases to reach 15. Thus, we expect no issues completing the phase 1 performance baseline and finalizing the match algorithm for the phase 2 RCT by the established contractual milestone of 10/1/17.

Our minimum target therapist sample is 44 PsycBC providers (all of whom will be over the age of 18 themselves, and treating patients within the age range of 18-65). Therapists will be psychologists, clinical counselors, and social workers. Recruitment will be coordinated among our UMass-employed project coordinator (PC), the PsycBC-employed PC, clinic staff members, and the Co-PIs. Specifically, the PsycBC team will verbally present information about the study (both phases 1 and 2) to their providers during staff meetings. Alternatively, this information can be presented through email. At this preliminary recruitment stage, this information will be used to heighten awareness about the study and to garner interest in participating. (The verbal script for staff meetings and the email text are included as phase 1 attachments to this protocol.) The PsycBC PC will then provide the UMass PC (via email) the names of providers who expressed interest in learning more about the study.

The UMass PC will subsequently contact interested therapist participants via email or teleconference (whichever is more convenient for the provider) to provide more study details/procedures and to direct the provider to an online consent form and survey. Providers remaining interested will access the secure study website to provide formal consent and to complete the baseline survey to which they will be directed after consenting. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral

manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the assessments in which their study patients will engage in both phase 1 (which is standard practice) and phase 2 (though they will not have access to the phase 2 research data at any time). Therapists will also need to consent to completing the aforementioned baseline survey prior to phase 1, as well as a few study-specific measures for each patient during the phase 2 RCT (the baseline survey and the phase 2 attachments are described in the relevant sections below and are included as phase 1 and 2 attachments, respectively, to this protocol). Relevant to phase 1, therapists will be compensated with a $20 Amazon gift card for the one-time completion of the online baseline survey, which will take no longer than 25 minutes to complete. Non-consenting therapists will receive case assignments as per standard care protocol and will simply not be included in the study (though we will analyze consenting and non-consenting therapists on demographic differences to see if any systematic sample bias exists).

Once therapists are enrolled in the study, the research team will access their naturalistically-collected TOP data to establish their performance across the minimum 15 cases to determine their personal strengths in treating patients across the risk-adjusted mental health problem domains measured by the TOP (recall that nothing changes in the therapist's service operation during this phase and, in fact, most of these TOP data points will have already been processed through ORI for cases seen by the providers in the past). Specifically, to establish therapists' performance track records, we will draw on each relevant patient's coded TOP data from baseline, week 8, and their termination point or week 16, whichever comes sooner (to mimic the definition of treatment outcome in the RCT phase discussed below). To reiterate, the research team is not formally enrolling patients into phase 1 of the study; rather, their coded data are simply processed by ORI, through its business agreement with PsycBC and its subcontractor role in the current project, to inform participating therapist report cards and the match algorithm).

Note that enrolled therapists will have an already-established TOP ID. This will allow the research team to link therapists? baseline survey data to their RCT data (i.e., responses to their own measures and their participating patients' measures) without use of any identifying information. As per customary precautions described below, a key that links therapist names and contract information with their data code will be kept in a separate, secure file that only trained research personnel can access.

Relevant phase 1 attachments to this protocol:

(1) Therapist recruitment materials: verbal script; email
(2) Therapist consent form and baseline phase 1 survey measures:

Provider Characteristics Form (PCF). This measure was developed by the research team to assess therapist demographic information, clinical experience, degree type, percent time seeing various patient types/diagnoses, any specialty training they have received, and dimensional ratings of the influence of various theoretical orientations on their treatment approach.

Therapist Perceived Strengths (TPS). This measure was developed by the research team to assess therapists' beliefs about their effectiveness in treating the various TOP domains when uninformed of their data-driven TOP track record. This measure will allow us to examine how accurate therapists are in perceiving their own strengths and weaknesses.

Phase 2: At this phase, the RCT will commence. The therapists will have already consented prior to phase 1 to be involved in the entire study, and they will know that patient data from their naturalistic baseline cases will have been used to create a personalized performance report card that will inform a prospective match with new patients they will treat in the trial. The therapists themselves will not see their report cards (as they will have been informed at the time of consent); rather, this information will be used by the research team with regard to the match manipulation.

Phase 2 marks the beginning of *patient* recruitment into the RCT. The patient population will be adult men and women (age 18-65) in PsycBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition based on TOP-derived presenting problem and to complete supplemental assessments (for monetary compensation, as per below) at baseline, at regular intervals during treatment, and at posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PsycBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, and poor quality of life. The only study-related patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*[48]) diagnoses. Our minimum study target sample size is 264 patients (6 per therapist).

We do not anticipate problems meeting our recruitment numbers in the project time frame, as PsycBC schedules approximately 950 new patients per month. Moreover, their care model already uses the TOP to screen patients for appropriate level of care, and, as a formal subcontract on the project, they are willing to use a patient-level-best-matched clinician list that is generated in real time (based on the predictive validity of our match algorithm). Including the randomization protocol into the treatment delivery model will not create any systemic barriers.

Patients will flow into PsycBC via electronic or self-referrals. At initial contact, the PsycBC PC will ask patients for permission to be contacted by study personnel (i.e., the UMass PC) if they are interested in learning more about participation (this verbal script remains included as a phase 2 attachment to this protocol). If they are, they will be asked by the PsycBC PC to sign an authorization agreement (included in the phase 2 consent form) to allow their contact information (name, email address, and phone number) to be shared with the research team. The PsycBC PC's role is restricted to this recruitment task and administration of authorization to release the limited PHI; thus, no PsycBC personnel will be engaged in human subjects' research.

The PsycBC PC will provide the UMass PC with a daily list of referrals who have provided signed authorization to be contacted about the study. The UMass PC will then contact eligible patients to schedule a baseline consent/assessment. If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a teleconference diagnostic interview via a secure platform with a trained graduate clinical psychology research assistant (RA). During this session, the RA will first review the study details/procedures and respond to any questions. Patients will be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience (via an exit interview). They will also be told that although their participation in the trial will largely mimic the same treatment that they would receive if they were not participating, they must consent to be randomized, complete extra study-specific measures (before, during, and after treatment), complete an audio-recorded diagnostic interview (before and after treatment), and accept assignment to a clinician who will deliver individual psychotherapy. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they request a transfer earlier, this will be treated as a dropout point for the sake of the trial.

If a patient consents to be enrolled, they will sign the consent form and complete a baseline survey of measures (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems, all described below in the listing of relevant phase 2 attachments to this protocol) through a secure online platform linked to their typical TOP administration. Next, the trained research assistant (RA) will administer (on the same individual teleconference) the *M.I.N.I. 7.0.2 International Neuropsychiatric Interview* (described below in the listing of relevant phase 2 attachments to this protocol). Following PsycBC's standard intake process and this research-focused baseline consent/assessment session, patients will be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match). For their involvement in the additional

diagnostic assessments and the additional measures that they will complete during the active treatment phase, patients will be compensated with a $50 Amazon gift card (on a prorated schedule for any missed assessments).

After the full baseline assessment, patients will be randomly assigned to condition (scientifically informed matched vs. pragmatic match) with a participating PsycBC provider. The UMass PC will generate the randomization sequences using an online random generator. Within condition, patients will be assigned sequentially to the therapists until they reach their study quota of 6 patients. Patients in the match condition will be assigned to therapists who have a demonstrated strength (derived from the baseline period) in treating, at a minimum, the patient's highest self-reported distress domain on the TOP-CS. Beyond the minimal match on the most elevated TOP-CS domain, our match algorithm will attempt to match patients to therapists on as many TOP-CS dimensions as possible, ultimately providing PsycBC with at least several well-matched choices for assignment within the match condition. In order to preserve this level of choice, there will be natural variability in the number of well-matched domains (some patients matched only on the minimum 1 TOP-CS domain, others matched on 2 or more domains). The match variability across both conditions will allow us to measure degree of match dimensionally as a moderator variable of our main treatment effect. Therapists will also be unaware of their patient's treatment condition (double blind), and they will treat both matched and non-matched patients (i.e., they will be crossed over the two conditions to minimize administrative disruptions). In the low probability event that there is no therapist meeting minimal match criteria for a patient in the match condition, that patient will be removed from the primary study analyses (though will, of course, still be offered treatment-as-usual at the clinic) and replaced with the next patient where a match does exist. As described in our power analysis below, we are oversampling in order to account for these "dropouts," or removed data points.

In addition to the baseline assessments already described, patients will be assessed via online surveys at regular intervals during treatment (the secure ORI platform will email hyperlinks to these surveys with reminders to complete them at the appropriate time intervals; the UMass PC can also follow-up with phone calls if needed). These during-treatment assessments will include the TOP-CS and measures of existential isolation and interpersonal problems at every odd-numbered week after the start of treatment, as well as global distress, therapeutic alliance quality, perceived treatment credibility, and outcome expectation after every even-numbered session (all measures of these constructs are described below in the listing of relevant phase 2 attachments to this protocol). During treatment, participating therapists will also be asked to complete their respective versions of the alliance and credibility/expectation measures (also at even-numbered weeks; the UMass PC will email hyperlinks to these online surveys with reminders to complete them at the appropriate time intervals; the PC will also follow-up with phone calls if needed). For completing these measures, therapists will be

compensated $50 per patient (again in the form of Amazon gift cards). All data collection will be coordinated through ORI, for which patients and therapists are assigned unique codes. Through their business agreement, ORI has direct access to PBC medical records; thus, it can push the relevant measures and track patient/therapist progress throughout the study.

As reminder, in both conditions, the providers will deliver treatment naturalistically (i.e., with no manipulation or influence from the research team). For the sake of the RCT, "treatment outcome" will be considered the point at which treatment terminates, or 16 weeks, whichever comes sooner. After the 16th week, or the termination session if it comes sooner, patients will complete posttreatment measures: the TOP-CS and TOP-CM, a measure of treatment satisfaction, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems (all described below in the listing of relevant phase 2 attachments to this protocol). Therapists will also document the nature of termination (measure described below in the listing of relevant phase 2 attachments to this protocol). Also at posttreatment, as defined by the trial, patients will undergo a repeat diagnostic telephone assessment (i.e., an RA-administered M.I.N.I., as described above).

We will also conduct a follow-up outcome assessment at 1 year after the patient's own termination on a randomly-selected subsample of 40 patients. Patients can easily be tracked in coordination with ORI and PsycBC; further, patients will have provided consent for this follow-up contact (should they be randomly chosen for it). At this assessment point, patients will again complete online the TOP-CS and TOP-CM, the brief measure of global distress, the measure of existential isolation, and the measure of interpersonal problems.

Note that all self-report measures (for both patients and therapists) at all time-points will be completed on Wi-Fi-connected tablets, or on home computers, through ORI's secure web-based platform. The TOP has its own dedicated website and HIPAA-compliant, secure server, and all other study-specific measures will be integrated into the TOP administration process.

We predict that the scientific match group will outperform the no match group to a clinically significant degree on TOP outcomes, global symptomatology, and interpersonal problems. We also expect that the match group will be more effective in promoting alliance quality and fostering more positive patient perceptions of treatment credibility and outcome expectation, all of which are established correlates (and candidate mechanisms) of positive treatment outcomes. Finally, we expect there to be less patient dropout in the match condition, and higher patient treatment satisfaction. Secondarily, we will examine 4 potential moderators of the expected between-group treatment effects on the primary TOP outcomes: (a) patient race (as it may be that the match algorithm is particularly potent, and an

important responsiveness tool, for historically understudied or underrepresented patients), (b) degree of match of therapist strengths to patient problems (rated dimensionally as a ratio given that therapists can be matched on more than just the minimum 1 domain, and the elimination of harmful matches for any distressed domain reported by the patient), (c) patient distress severity, and (d) complexity of patient presenting problem. Thus, we will test if matching is only, or particularly, effective under the conditions of a central patient characteristic, a multiple domain match, and/or for patients with the most severe or complex pathology. As noted, we will also assess therapists' self-perceived strengths on the TOP domains. We expect to replicate previous literature showing that therapists are poor judges of their own efficacy, tending to underestimate negative effects and overestimate positive effects with their patients (Lambert, 2011), which would further underscore the importance of a data-driven match process.

Finally, for a subsample of stakeholders, we will conduct post-trial exit interviews (*N*s = 5 patients, 5 therapists) to gather invaluable input on how to be responsive to the study findings in terms of dissemination, implementation, and policymaking, including the potential importance of integrating diagnosis, provider age, race, or gender into subsequent matching approaches. We will recruit stakeholders in order of completion until we reach our target *N*s (therapists can only be involved once they have treated all 6 of their study patients). There are no other inclusion/exclusion criteria for the exit interviews; we will simply stop asking if participants are interested once we have reached our target Ns. This is consistent with the study consent forms, which clearly state that interested participants may be selected to engage in the interview.

Fully reflecting stakeholder engagement, and to eliminate any biases or power dynamics introduced by the PIs or their research staff, Advisory Board members (with appropriate credentialing for working with human subjects) will conduct the individual interviews. The PIs (Constantino & Boswell) will train 3 Advisory Board members on qualitative interviewing, and each will administer 1-2 pilot interviews as part of the training, plus 5 study interviews. The interviews will be conducted and audiorecorded via a secure webconferencing service and will last approximately 45-60 minutes. Participants will be compensated with a $100 Amazon gift card for their time. RAs will transcribe the interviews, removing any identifying patient information. These RAs will also conduct a qualitative analysis of these text-based data.

Relevant phase 2 attachments to this protocol:

(1) Patient phase 2 recruitment verbal script
(2) Patient phase 2 consent form and phase 2 baseline measures packet:

TOP-Consumer Registration Form (TOP-CR; Kraus et al., 2005). The TOP-CR will be used routinely during the phase 1 baseline (and the phase 2 RCT) to assess patient demographics. On this form, patients indicate their age, gender, ethnicity, marital status, income level, employment status, religious identification, education level, general health status, and medical and mental health treatment history.

TOP-Clinical Scales and Case Mix (TOP-CS & TOP-CM; Kraus et al., 2005). This is the primary measure in our study; it will be used to establish the therapist report cards during the baseline phase to inform the match manipulation in phase 2. It also tracks patient outcomes. The TOP-CS consists of 58 items assessing 12 symptom and functional (including strengths) domains (risk-adjusted for case mix variables assessed via 37 items on the companion TOP-CM, such as divorce, job loss, comorbidity): work functioning, sexual functioning, social conflict, depression, panic (somatic anxiety), psychosis, suicidal ideation, violence, mania, sleep, substance abuse, and quality of life. Global symptom severity is assessed by summing all items or by averaging the z-scores (i.e., standard deviation units relative to the general population mean) across each of the 12 clinical scales. Domain-specific symptom severity is quantified as the individual z-scores for each clinical scale using general population means and standard deviations for the conversion. The TOP-CS has been shown to have excellent factorial structure, as well as good test-retest reliability across all scales. It is sensitive to change while possessing limited floor and ceiling effects (Kraus et al., 2005). The TOP also has demonstrated good convergent validity with scales like the Beck Depression Inventory (Beck, Steer, & Brown, 1996) and the Brief Symptom Inventory (Derogatis, 1975).

Symptom Checklist-10 (SCL-10; Rosen, Drescher, Moos, & Gusman, 1999). To evaluate outcome with an index separate from the TOP (to test convergence and enhance the validity of any between condition effects), we will also assess global distress with the SCL-10, a 10-item, well-validated and widely used self-report inventory that assesses psychological wellbeing.

Existential Isolation Scale (EIS; Pinel et al., 2014). To assess this isolation subtype, participants will complete the EIS, a six-item scale that requires participants to rate the extent to which they agree with items such as “I often have the same reactions to things as other people around me do” (reverse-coded) and “Other people usually do not understand my experiences” and “People often have the same ‘take’ or perspective on things that I do” (reverse-coded). Participants respond using a 7-point scale. The EIS has high internal consistency, and has been validated extensively (Pinel et al., 2014).

Inventory of Interpersonal Problems-32 (IIP-32; Horowitz, Alden, Wiggins, & Pincus, 2000). To assess interpersonal problems, participants will complete the 32-item circumplex version of the IIP. This widely used instrument reflects interpersonal inhibitions and excesses, with each item rated on a 5-point scale. Higher total scores

indicate more interpersonal problems. The IIP-32 also has 8 subscales (Domineering, Vindictive, Intrusive, Cold, Socially Inhibited, Nonassertive, Overly Accommodating, and Self-Sacrificing) that comprise a circumplex of problematic interpersonal behavior around the main interpersonal dimensions of affiliation and control. Like the original measure (Horowitz, Rosenberg, Baer, Ureno, & Villansenor, 1988), the IIP-32 has evidenced good psychometric properties.

(3) RA administered diagnostic assessment (baseline and posttreatment):

M.I.N.I. 7.0.2 International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al., 2016). The M.I.N.I. is a brief, structured diagnostic interview for DSM-5 and International Classification of Diseases (ICD; World Health Organization, 2008) psychiatric disorder classification. With its administration time of approximately 15 minutes, the M.I.N.I. is the psychiatric interview of choice in clinical trials and epidemiological studies. Despite its brevity, its psychometric properties compare favorably to longer instruments like the *Structured Clinical Interview for DSM* (SCID; First, Spitzer, Gibbon, & Williams, 1996). As part of the diagnostic evaluation, the RAs will complete the *Clinical Global Impression* (CGI), a widely used observer-rated scale that includes a 0-7 judgment of illness severity for which higher scores indicate more extreme illness.

(4) Patient phase 2 during-treatment measures:

TOP-CS, SCL-10, EIS, IIP-32. All described previously.

Working Alliance Inventory-Short Form, patient version (WAI-SF-P; Tracey, & Kokotovic, 1989). The WAI is the most widely used alliance measure, assessing patient-therapist agreement on the goals and tasks of treatment, and the quality of their relational bond. This 12-item short form, assessing these dimensions from the patient's perspective, has demonstrated sound psychometric properties.

Credibility/Expectancy Scale, patient version (CEQ; Devilly & Borkovec, 2000). The CEQ is the most widely used and psychometrically sound measure of the patient's perceived logicalness of a given treatment and expectation for the personal efficacy of that treatment.

(5) Therapist phase 2 during-treatment measures:

Working Alliance Inventory-Short Form, therapist version (WAI-SF-T; Tracey & Kokotovic, 1989). This is the parallel version of the WAI-SF described above, though now as rated from the therapist's perspective.

Credibility/Expectancy Scale, therapist version (CEQ; Devilly & Borkovec, 2000). This is the parallel version of the CEQ described above, though now as rated from the

therapist's perspective (i.e., the therapist's sense of how logical the patient sees the treatment and how optimistic the patient is about receiving benefit from it).

(6) Patient phase 2 posttreatment measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

TOP-Satisfaction with the Treatment Process (TOP-STP; Kraus et al., 2005). This 32-item measure assesses patient's satisfaction with their provider, the treatment they received, and the treatment milieu (e.g., staff, other patients, etc.).

(7) Therapist phase 2 posttreatment measure:

Nature of Termination Form (NTF). This measure was developed by the research team to assess the nature of patients' termination from the provider's open-ended perspective, as well as through a choice format of unilateral/patient-generated, unilateral/therapist-generated, or mutual. Therapists can also describe in an open-ended format any unusual or noteworthy circumstances that may have led to the termination of therapy with this client (e.g., transfer of client to another therapist).

(8) Patient phase 2 subsample follow-up measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

(9) Stakeholder exit interview protocols (patient and therapist versions)

b. State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

For the baseline and posttreatment patient assessments during phase 2, RAs will administer via teleconference the semi-structured diagnostic interview (M.I.N.I.), which will be audiorecorded. This will allow a different RA to review the recording and to make independent diagnostic and symptom severity determinations. With these two sets of ratings, we can then calculate interrater reliability on baseline and posttreatment diagnosis.

Audio recordings from the baseline diagnostic assessments will be digitally stored through the secure web-conferencing service. All data will be encrypted and password protected. Only the necessary research team members will know the login and password information and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings. The RAs, of course, will have completed the mandatory ethics training in human subjects' research, data management, and HIPAA compliance. These RAs will be independent evaluators who will not have

access to other therapist or patient data. The recordings themselves will not be labeled with any identifiable information. The PI will routinely monitor the collection and analysis of recorded data.

After the recordings have been assessed for diagnostic reliability, the files will be securely deleted by the sponsored project contract term date of 6/16/20. No audio data or identifiable text data stemming from the recordings will be presented at meetings or in published articles. Only the reliability coefficients will be disseminated with the results of the full trial.

c. State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #11 (Attachments).
Although the protocol does not involve deception, it does involve incomplete disclosure in Phase 2 given that participants are not given all of the information about the study until debriefing. Thus, in the debriefing form, we now provide participants the opportunity to withdraw their data upon learning the full scope of the research.

3. Background

a. Describe past findings leading to the formulation of the study.
Research has consistently identified significant variability in skill and outcomes between therapists (Baldwin & Imel, 2013; Boswell et al., 2013; Westra, Constantino, Arkowitz, & Dozois, 2011), even when therapists utilize an empirically supported treatment (EST). In fact, differences between treatment providers account for a greater portion of treatment outcome variance than the specific interventions delivered in controlled trials (Krause, Lutz, & Saunders, 2007; Wampold & Imel, 2015). Thus, improvements in MHC can occur by identifying effective providers in addition to promoting ESTs (Kraus et al., 2007).

In the largest study to date on this topic, our team investigated therapists' naturalistic treatment outcomes over many different problem domains (e.g., depression, anxiety, substance use, mania, sleep) in a sample of 6,960 patients and nearly 700 providers (Kraus, Castonguay, Boswell, Nordberg, & Hayes, 2011). The majority of therapists demonstrated a differential pattern of effectiveness depending on the problem domain, and therapist domain-specific effectiveness correlated poorly across domains suggesting that therapist competencies may be domain-specific, rather than reflecting a core attribute or general underlying therapeutic skill. Importantly, although some therapists demonstrated effectiveness over multiple problem domains, no therapists demonstrated reliable effectiveness across all domains. Further, a small, but notable 4% of the therapists did not demonstrate effective outcomes on any domain. These data suggest that in any population of therapists (payer network, hospital, or community mental health

system), there is an opportunity for behavioral health to do what medicine did decades ago – encourage provider specialization. Virtually every clinician has an area where they are above average (82-96%; Kraus et al., 2011, 2016), and our research suggests that if they specialize to their unique skills, population-level outcomes (i.e., symptom reduction, behavior change, increased functionality) will improve dramatically. This would reflect a major, and likely highly impactful shift to current MHC systems.

However, patients and referrers are typically unaware of the unique track record ("report cards") of local-area providers, which represents a critical gap in knowledge transfer within the MHC system. Without systematically collecting and disseminating performance report cards, stakeholders (e.g., patients, therapists, administrators responsible for case assignment, primary care physicians) lack vital information on which to base MHC choices and referral decisions, and that can inform personalized treatment (Boswell, Constantino, Kraus, Bugatti, & Oswald, 2015). Conversely, there is potentially immense advantage to matching patients to providers based on scientific outcome data (Constantino, Boswell, Bernecker, & Castonguay, 2013).

Consistent with this notion, the Institute of Medicine (IOM) has made recommendations to: (a) customize care based on the patient's needs, (b) share knowledge, (c) engage in data-driven decision-making, (d) promote transparency (including information on performance and patient satisfaction; Kohn, Saxena, Levav, & Saraceno, 2004), and (e) use valid and reliable assessment instruments to assess progress and to aid decision-making. The IOM has also recommended that MHC patients be provided with information on the quality of practitioner care (e.g., provider report cards) and use this information when making treatment decisions. Importantly, we have survey data that point to MHC patients, therapists, and administrators endorsing such applied knowledge transfer as a high priority (Boswell et al., 2015). Provider track record report cards are meaningful data to the MHC patient population, as are the mental health benefits that could stem from being well matched to provider.

We have developed over the past 20 years an innovative, technology-based mechanism/intervention to deliver report cards and drive this match concept within a patient-centered MHC model (Kraus et al., 2011). Our longitudinal data suggest that our match algorithm, based on our multidimensional outcome tool (the TOP) is efficacious for MHC outcomes. In addition to our study highlighted above (Kraus et al., 2011), a more recent prospective study of 59 therapists and 3,540 patients resulted in a between-treatment controlled Cohen's d effect size of .80 (Kraus et al., 2016). Each therapist's first 30 patients were used to classify a therapist's skills in the 12 domains of symptoms and functioning as either statistically above average, average, or below average. The best matching algorithm functioned as follows: for each new, successive patient, he or she was classified as well-matched if the risk of harm was eliminated (i.e., the therapist was not below average when treating any

elevated domain) and the therapist was above average in treating the patient's three most out-of-the-norm domains (e.g., depression, suicidality, and panic). Poorly matched patients had below average outcomes, with small effect sizes (d = .30) Well-matched patients, by contrast, achieved very large pre- vs. posttreatment effect sizes of d = 1.19. These data lend strong support that the proposed comparative effective research (CER) will yield similar results (i.e., increased efficacy and reduced harm) in realigning the skills of a large population of therapists in one of the forerunner Accountable Care Organizations (our partner Atrius) when matching empirically derived therapist skills with patient need. The technology/intervention is well established, it has demonstrated efficacy, and awaits investigation in a well-powered RCT.

4. Subject Population

a. State how many subjects you propose to use and state the rationale for the proposed number.

For the primary 3-level hierarchical model assessing treatment condition effects at the patient level on linear change rates within patients, we used Raudenbush and Liu's (2001) formula as incorporated in the Optimal Design program to determine the minimum numbers of therapists and patients needed to detect a moderate effect of condition (standardized difference between change rates = .50). With a minimum of 6 measurements spaced over the maximum 16 treatment weeks and assuming 5 patients per therapist, an intra-class correlation of .15, and an alpha of .05, we will need a total of 44 therapists and 220 patients to achieve a power of .80 to detect moderate condition effects on linear change rates. Factoring a 20% dropout rate at the patient level, running our experiment on 264 patients (6 per therapist) should provide sufficient statistical power to detect group differences on our primary outcome variables.

To summarize, based on this power analysis, we will for phase 1 access a naturalistic baseline assessment of a minimum of 44 consenting therapists' performance across a minimum of 15 cases to determine their strengths in treating the risk-adjusted domains measured by the TOP. We will then recruit a minimum of 264 patients for the phase 2 trial, assigning patients to the same 44 therapists who participated in phase 1 (they will see 6 cases each during the trial).

b. Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, professors, subjects with learning disabilities, mental health disorders, etc.). Please incorporate specific inclusion/exclusion criteria (e.g. physical and psychological health, demographic information, or other unique characteristics).

Therapist participants: As noted, our target sample is 44 therapist participants (age *range* = 30-65 years) who will be social workers, psychologists, and licensed clinical counselors. Reflecting PsycBC's therapist pool demographics, we anticipate that our

provider sample will break down as follows: approximately 70% will be female; 88% will be white/non-Hispanic, 3% Black, 2% Hispanic, 2% "Other/mixed," and 5% Asian. Based on these projections and our power analysis, our targeted/planned therapist enrollment is indicated in an attached Targeted/Planned Enrollment Table (Therapists).

Patient participants: Patient participants will be 264 adult men and women (age 18-65) in PsycBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation) at baseline, at regular intervals during treatment, and at posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PsycBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, and poor quality of life. The only study-related, patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*) diagnoses. The composition of our sample will roughly match the average utilization data for age, gender, and race/ethnicity at PsycBC. Based on these projections and our power analysis, our targeted/planned patient enrollment is attached in an Estimated Final Racial/Ethnic and Gender Enrollment Table (Patients).

c. State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.

We are not specifically targeting these specific vulnerable populations, and our research design and/or the PsycBC care system will specifically exclude minors and prisoners. However, given the effectiveness design focused on maximizing ecological validity, some of our patients are sure to have economic and educational vulnerabilities, which are risk factors for mental health issues. Some women might also be pregnant.

d. If women, minorities, or minors are not included, a clear compelling rationale must be provided.

Minors will be excluded because they are typically not solely responsible for their own treatment decisions, and the outcome measure used in this study, and on which the match manipulation is based, focuses on adults.

e. State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.

N/A

f. State the number, if any, of subjects who are involved in research conducted abroad and describe any unique cultural, economic or political conditions.
N/A

g. Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach advertisements, flyers, etc. in Section #11 (Attachments). Note: Potential subjects may not be contacted before IRB approval.
Therapist participants:

Recruitment will be coordinated among our UMass-employed PC, the PsycBC-employed PC, clinic staff members, and the Co-PIs, and will involve presenting information about the study (both phases 1 and 2) to providers through verbal script at staff meetings or by email. At this preliminary recruitment stage, this information will be used to heighten awareness about the study and to garner interest in participating. The PsycBC PC will then provide the UMass PC (via email) the names of providers who expressed interest in learning more about the study. The UMass PC will subsequently contact interested therapist participants via email or teleconference (whichever is more convenient for the provider) to provide more study details/procedures and to direct the provider to an online consent form and survey. Providers remaining interested will access the secure study website to provide formal consent and to complete the baseline survey to which they will be directed after consenting. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the assessments in which their study patients will engage in both phase 1 (which is standard practice) and phase 2 (though they will not have access to the phase 2 research data at any time). Therapists will also need to consent to completing the aforementioned baseline survey prior to phase 1, as well as a few study-specific measures for each patient during the phase 2 RCT.

Patient participants:

Phase 2 marks the beginning of *patient* recruitment into the RCT. Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation). Patients will flow into PsycBC via electronic or self-referrals. At initial contact, the PsycBC PC will ask patients for permission to be contacted by study personnel (i.e., the UMass PC) if they are interested in learning more about participation. If they are, they will be asked by the PsycBC PC to sign an authorization agreement (included in the consent form) to allow their contact information to be shared with the research team. The

PsycBC PC's role is restricted to this recruitment task and administration of authorization to release the limited PHI; thus, no PsycBC personnel will be engaged in human subjects' research.

The PsycBC PC will provide the UMass PC with a daily list of referrals who have provided signed authorization to be contacted about the study. The UMass PC will then contact eligible patients to schedule a baseline consent/assessment. If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a teleconference diagnostic interview via a secure platform with a trained graduate clinical psychology research assistant (RA). During this session, the RA will first review the study details/procedures and respond to any questions. Patients will be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience (via an exit interview). They will also be told that although their participation in the trial will largely mimic the same treatment that they would receive if they were not participating, they must consent to be randomized, complete extra study-specific measures (before, during, and after treatment), complete an audio-recorded diagnostic interview (before and after treatment), and accept assignment to a clinician who will deliver individual psychotherapy. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they request a transfer earlier, this will be treated as a dropout point for the sake of the trial. If the patient consents to be enrolled, they will sign the consent form and complete a baseline survey of measures (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems) through a secure online platform linked to their typical TOP administration. Next, the trained RA will administer (on the same individual teleconference) the M.I.N.I. Following PsycBC's standard intake process and this research-focused baseline consent/assessment session, patients will be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match).

h. Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.
Therapist participants:

Therapists will complete, in no longer than 25 minutes, a few study-specific measures as part of a phase 1 baseline survey for which they will be compensated $20 in total (in the form of an Amazon gift card).

During Phase 2, therapists will also complete a few study-specific measures throughout treatment with each of the 6 participating patients treated during the

phase 2 RCT; they will be compensated $50 per patient for this additional, but minimal, time burden. The compensation will again be in the form of an Amazon gift card.

If therapists complete their measurement schedule through all possible contact points for a given participating patient (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination for a participating patient that occurs prior to week 16 of treatment, they will receive full compensation (i.e., a $50 gift card for that patient).

However, if a therapist withdraws from the study, they will have the option to be compensated on a prorated basis for the measures that they have already completed regarding each of their participating patients. This proration works out to approximately $3 per week for a participating patient, which will be deducted for the number of weeks "missing" from therapists' assessment schedule (i.e., based on the point at which the therapist withdrew from the study). For example, if a therapist completes the measurement schedule for a given patient through week 8 (9 weeks, including baseline) and then withdraws from the study, they will have "missed" 8 weeks of data collection for that participating patient. Their compensation for this participating patient will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26. This adjustment will be completed for any and all relevant participating patients. To summarize, therapists who withdraw from the study will have the option either to (a) receive their relevant prorated compensation, or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the therapist participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Patient participants:

Patients in Phase 2 will undergo a semi-structured diagnostic interview at both baseline and posttreatment, as well as complete several study specific measures throughout treatment (and, if randomly selected, at a follow up); they will be compensated $50 total for these non-routine aspects of their care. The compensation will be in the form of an Amazon gift card. If patients complete their measurement schedule through all possible contact points (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination that occurs prior to week 16 of treatment, they will receive full compensation. However, if they drop out of treatment prior to week 16, and their end point was not a planned termination that can be considered posttreatment for the purpose of the study, compensation will occur on prorated schedule. This works out to approximately $3 per week, which will be deducted for the number of weeks "missing" from the schedule. For example, if a patient completes the measurement

schedule through week 8 (9 weeks, including baseline), and they did not engage in a planned termination, they will have "missed" 8 weeks of data collection. Their compensation will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26.

Patients who withdraw from the study (which is distinct from simply dropping out of treatment) will be given the option to (a) receive prorated compensation for the completion of measures up until the point of withdrawal (following the proration schedule outline above), or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the patient participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Finally, note that in the event that a participant (either a patient or therapist) withdraws from the study during phase 2, the other dyad member (either the patients seen by a withdrawing therapist or the therapist treating a withdrawing patient) will not be penalized; that is, as long as they have already consented to the study, they will receive the full amount of reimbursement (i.e., a $50 gift card) regardless of the point at which their patient/therapist withdraws. However, note that consistent with the wishes of the participant, we will, of course, stop collecting data at the point of withdrawal (i.e., if therapists withdraw, we will stop collecting data from their patients who will be compensated fully; if patients withdraw, we will stop collecting data from their therapist regarding that patient and the therapist will be compensated fully for that patient).

i. **Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be 1-session for a total of 90 minutes).**
A) The project is funded in the form a cost-reimbursement contract for which a specific milestone schedule exists. The contract start date is 9/15/16 and the contract term date is 6/15/20. All analyses will be completed by the term date. Details are available in the attached updated milestone schedule.

B) Therapist subjects will be involved for 2 months in phase 1, as well as through the phase 2 trial (approximately 2 years, though with variability depending on when they have been assigned and have treated their 6 study cases). Patients in phase 2 only will be involved in the study protocol through their actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after termination on a randomly-selected subsample of 40 patients).

5. Risks

HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." This also includes risks to subject confidentiality and any discomforts, hazards, or inconveniences.

For the categories below, include a description of risks.

a. **Describe the risks related to:**
   Physical well-being
   None anticipated.

   Psychological well-being
   Regardless of condition, PsycBC will employ its usual triage assessments, therapists will employ their usual treatments, and patients will be receiving their usual care. Consequently, there are no risks from our research protocol over and above what would normally be expected in routine assessment and psychotherapy, and PsycBC has its usual clinical and safety protocols in place (and the clinical personnel to execute them).

   In treatment, some individuals may experience emotional upset during sessions. Additionally, some participants may experience disappointment with their rate of progress or setbacks. The risk associated with such reactions will be addressed clinically by the therapists who are treating these issues and who have peer and administrative support. To reiterate, these treatment risks would occur in the course of treatment-as-usual. These are not additional risks stemming from the research protocol. Further, the TOP outcome monitoring system, which is at the center of our research project, is already being used by PsycBC providers without incident.

   As is typical in psychological research, some of the assessment questions from the research measures may be experienced as intrusive and/or may cause anxiety. The risk from such increased anxiety, however, is mitigated by the use of skilled and extensively trained assessors who are aware that such reactions may be related to a person's presenting problems, or simply a function of the intimate and emotionally intense nature of psychological services. In addition, the PIs, PCs, and/or PsycBC staff and administrators will be available to meet with any participant who may be unduly disturbed due to the few research tasks. Because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and email address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address (which they will request verbally, if necessary) for emergency response. The RA, if

applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

Economic well-being
Given that therapist performance data are being collected, it is reasonable to be concerned about possible employment implications were an employer (i.e., clinic administrator) to attempt to interpret study information incompletely (i.e., infer lack of therapist effectiveness to the point of questioning employability). This risk, however, is extremely minimal for the following reasons:

(1) As a condition of being involved in the study, clinic administrators will be required to agree that therapists' participation or non-participation in this research will in no way affect their standing/employment at their community mental health clinic.

(2) The research team will not reveal therapist performance data to clinic administrators or staff members; that is, the study could be considered "triple-blind." Neither patients nor therapists will know when they are in an experimentally-matched vs. typically-matched dyad, and administrators/staff members will not have access to the therapists' report cards.

(3) However, administrators and staff members are required to be in the know about well-matched therapist "short-lists," as this is essential to the research design; that is, when patients are randomized to a well-matched therapist, those potential therapists need to be identifiable. It is possible that administrators or staff members might misinterpret these data to suggest that a given therapist is ineffective (if he or she is never or rarely showing up on a shortlist). However, we will guard against this misinterpretation by educating administrators and staff members that the shortlist only represents, in a small cross-section of time, therapists that have been shown to be effective on at least 1 of 14 domains, which represents a given patient's most severe problem at that time (the match criterion). We will stress that this does not mean that a therapist is globally ineffective. It may just be that patients randomly assigned to the match group are tending not to have the types of problems for which a given therapist is relatively effective. That therapist, though, could be highly effective at treating one or even many other domains.

(4) Finally, administrators and staff members will not be told which therapists are or are not participating in the study. Thus, lack of being on a shortlist, for all that they will know (unless a therapist openly reveals that he or she is participating in the study), could simply connote a choice to not participate in the project.

Social well-being
None anticipated.

Breach of confidentiality (including audio/video taping)
A breach of confidentiality represents a risk, but every step will be taken to minimize this risk. PsycBC and ORI routinely handle PHI and are in compliance with HIPAA regulations. Any "hard" materials (e.g., diagnostic assessment summaries) that are collected for research purposes only will be stored in a locked cabinet in the PI's Psychotherapy Research Lab. There will be no hard copy data collected at the PsycBC clinic sites. Most of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Finally, digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted

b. For research conducted internationally, describe any political or sociocultural considerations that may affect your research design (for example, in some communities it may not be customary to sign documents, etc.)
N/A

c. Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.
The Co-PIs, project coordinator, PsycBC staff members, and PsycBC administrators will monitor the treatments and data collection; thus, they can assist in regularly monitoring any adverse events. Such negative occurrences are unlikely to be trial-related, as all patients will be receiving treatment-as-usual. Therefore, any adverse event will be addressed with PsycBC's well-established procedures for monitoring services and managing treatment-related disturbances. Nevertheless, any adverse event will be recorded and immediately reported to the IRB (UMass), PCORI (funder), and the project's Data Safety and Monitoring Board (DSMB).

Should, during the course of the study, a patient show evidence of psychological or physical deterioration, the patient will be assessed comprehensively in the domains of concern (except in the case of a life-threatening physical emergency, such as the emergence of acute chest pain, in which case 9-1-1 will be called immediately). If the therapist deems that the patient meets criteria for a psychiatric hold (e.g., patient is an imminent danger to self or others), the therapist will arrange for the patient to be brought to the emergency department and will contact his/her PsycBC administrator and the PI to debrief. If a patient is not meeting criteria for a psychiatric hold, but is showing clear signs of decreased mental status, the therapist will continue to meet with the patient, as well as - in consultation with the PsycBC administrator - make arrangements for the most appropriate level of care.

As noted, because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed

clinical psychologists and mental health care providers) will have the patient's contact information (phone number and email address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address (which they will request verbally, if necessary) for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

6. Benefits

a. Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).

The most direct benefit a participant in this study may receive is the reduction of symptom-related distress and improved functioning. In addition, patients (especially those in the match condition) will receive more personalized MHC. Psychotherapists (especially those in the match condition) may experience a greater level of positive impact across their caseloads. Given that the actual treatments being provided will not be manipulated, the benefits of participation are judged to far outweigh the potential study-specific risks.

There is immense potential for future therapists and patients to benefit from the results of this study; if the hypotheses are supported, there will be cause for substantial revamping of MHC systems to capitalize on matching patients to therapists who have an empirically demonstrable track record of strength in treating patients with similar presenting problems.

7. Procedures to Maintain Confidentiality

a. Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.

Multiple steps will be taken to protect confidentiality. As mentioned, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy data collected at the PsychBC sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted.

Only designated study personnel will have access to identifiable, study specific, private information about human subjects. When registering on the TOP system, as

required by PsychBC's standard operating procedures, both patients and therapists are assigned a random number code that links all subsequent assessments and is separated from identifiable information. This random number code will function as each participant's study code and will be used to link participants' data. As noted, all therapist and patient data (outside of diagnostic assessment summaries and the TOP administrations) will be collected through a web-based platform. The assigned participant code will be used to link/aggregate information, so private information will not be requested after the baseline assessment/consent process. Only the PI and essential research staff will have access to the list that links identifiable information with the participant's study code. Any audio recordings will be encrypted and password protected. Only the Co-PIs will know this password and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings; however, they will not have access to additional identifiable information (only the information required to complete the analysis). For any data used for research and publication purposes, the confidentiality of participant information will be ensured.

b. If information derived from the study will be provided to a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

The PI is required to submit information (i.e., contractual "deliverables") on a regular basis to PCORI (the study sponsor), including IRB protocols, interim progress reports, advisory board meeting minutes, engagement plan updates, evidence of diagnostic criterion reliability from training cases, interim data reports, presentation abstracts and documentation of acceptance, manuscript copies, letters of endorsement from scientific and consumer groups, final data analysis summary, and final research report. Details on deliverables are available in the aforementioned (and attached and updated) milestone schedule. No PHI will be transmitted to PCORI.

c. Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.

As noted, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy research-only data collected at the PsycBC sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. Digital recordings of diagnostic assessments will be stored in a password protected website, and securely deleted by the project contract's term date. Only the relevant members of the research team will have access to the participants' data and only the PI will have long-term access to identifiable information. As noted, all assessments will be linked with a participant code. Any records linking the code to the participant's name or voice recording will be kept in a separate locked file cabinet in the PI's office. These records will be destroyed 5 years after the contract term date.

8. Potential Conflict of Interest

a. Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)? Y

b. Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment? N

c. Is any Investigator(s) a member of an advisory board with the Sponsoring company? N

d. Do any investigators receive gift funds from the Sponsoring company? N

e. Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol? Y

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner. If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. If you answer yes to any of the questions above, please go to the policies for more information.

9. Informed Consent

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below, for each Consent Form(s), Alteration Form(s), and Waiver(s).

9.1. Consent Form – therapist consent form revised

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
UMass personnel only: either the PC or an RA.

How is consent being obtained?

Therapists will meet or speak via teleconference with the UMass PC or an RA to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
The PI and his collaborators will provide close oversight of the entire protocol, including regular consultations with a study Advisory Board and the DSMB.

9.2. Consent Form – therapist exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a therapist agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the therapist will be directed. Coercion will be minimized by clearly stating that participation is voluntary.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
If the interviewer interacts with a therapist who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the interview protocol.

9.3. Consent Form – patient consent form revised

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
UMass personnel only: either the PC or an RA.

How is consent being obtained?
If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a telephone diagnostic interview with a trained graduate clinical psychology RA (employed at either UMass or University at Albany). The RAs will first review the study details/procedures and obtain consent through an online baseline survey to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?

Competency for making one's own treatment decisions will be an inclusion criterion for the study. Moreover, if a clinic staff member, the PC, or an RA interacts with a patient who appears to have competency issues in the decision-making process for engaging in the study, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the study. The DSMB will be consulted if appropriate.

9.4. Consent Form – patient exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a patient agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will have been an inclusion criterion for the main study. Moreover, if the interviewer interacts with a patient who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the interview protocol. The DSMB will be consulted if appropriate.

10. Assent Background

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

11. Attachments

Document Type	Document Name	Attached Date
Questionnaires	Patient Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	Therapist Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	TOP-STP	10/04/2016

Questionnaires	Stakeholder Exit Interview Protocols	10/04/2016
Federal Grant/Sub-contract	PCORI IHS-1503-28573_Constantino_executed contract	10/04/2016
Federal Grant/Sub-contract	PCORI Original Contract Proposal_all sections	10/04/2016
Other	Constantino Lab Personnel Link- Google Docs	10/04/2016
Other	PCORI_Phase 2_Patient Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Patient Data Collection Reminder Call Script	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Reminder Call Script	11/13/2016
Questionnaires	MINI 7.0.2 Standard	11/13/2016
Advertisements	PCORI_Clinician Recruitment_Verbal Script_REVISED_clean	08/13/2017
Advertisements	PCORI_Clinician Recruitment_Email_REVISED_clean	08/13/2017
Advertisements	PCORI_Patient Recruitment_Verbal Script_REVISED_clean	08/13/2017
Questionnaires	PCORI_Clinician Consent & Baseline Measures Packet_REVISED	08/13/2017
Questionnaires	PCORI_Patient Consent & Baseline Measures Packet_REVISED	08/13/2017
Questionnaires	PCORI_Patient Posttreatment Measures Packet_REVISED w. debriefing form	08/13/2017
Questionnaires	PCORI_Clinician Posttreatment Measures Packet_REVISED w. debriefing form	08/13/2017
Questionnaires	TOP-CS & TOP-CM	08/13/2017

Other	PCORI_Targeted Enrollment Tables_REVISED_clean	08/13/2017
Other	PCORI Milestone Schedule_REVISED	08/13/2017
Other	Participant Flow_REVISED	08/13/2017
Other	Data Collection Schedule Revised	08/13/2017
Federal Grant/Sub-contract	Constantino_IHS1503-28573_Mod 001 SUB_FE 20170808_FINAL EXECUTED MOD	08/13/2017
Other	PCORI IRB Proposal_R1_for PsycBC_FINAL submitted	08/13/2017
Other	ORI-PBC_Business Associate Agreement	08/13/2017

Obligations

Obligations of the Principal Investigator are: Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes; Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded; Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days; Continuing Review – IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.” Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events/Unanticipated Problems - All events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than five (5) working days; Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.”

The Principal Investigator has read and agrees to abide by the above obligations. Y

C. Summary of the 2nd formal modification to the PCORI contract (September 2018), and the full revised study protocol (2nd revision) submitted to, and approved by, the University of Massachusetts Amherst Institutional Review Board (March 2018)

CONTRACT MODIFICATION SUMMARY

On September 14, 2018, PCORI approved the 2nd contract modification (IHS-1503-28573 Modification 002), which included the following changes – all in the service of boosting patient recruitment and retention:

- We increased the number of PsycBC telephone intake specialists who were trained to recruit and assign study patients. This increased the number of potential patients who could be recruited to the study on any given day.

- We revised the language of the study script/pitch that the PsycBC telephone intake specialists used to recruit patients. This revision better emphasized how completing a routine outcome measure was already standard practice at PsycBC, and how completing such a measure at intake could improve a patient's quality of care through personalized matching to providers. This immediately normalized the measurement process as part of usual care, and it highlighted personalized care over participant burden. In fact, the entire first part of the recruitment pitch had to do with clinical care; the introduction of the study came after, and it was billed as an opportunity to be part of an ongoing project on this personalized care notion and to earn financial compensation for doing so.

- PsycBC began offering periodic incentives (in the form of a payment bonus or tickets to local events) to the intake specialist who successfully directed the most patients to our online study consent form in a given period of time (e.g., a 1-week competition). This bonus was completely unrelated to the project budget; it was a motivational strategy within their own payroll system.

- We started offering a $15 recruitment incentive. This compensation incentivized patients' willingness to leave the initial intake call to review the study consent form. We felt that this would be useful given that a high percentage of people were enrolling *if* they reviewed the materials. However, getting potential participants to agree to review the form was an early challenge.

- We eliminated the diagnostic interview calls (using the M.I.N.I.), as these assessments were providing little yield and may have been perceived as off-putting and burdensome. In practice, many early patients who enrolled in the study were failing to keep their baseline telephone assessment appointment with our research assistants. Although we regularly followed up to reschedule, we feared that these potentially burdensome assessments were posing a risk to retention. Moreover, even if it was not leading to a patient dropping out of the study, many enrolled patients were completing all

assessments *other than* the M.I.N.I., which was resulting in missing data regardless. We also wondered whether when people read the consent form and saw that we were asking them to engage in two 30-minute phone calls in addition to completing measures, this may have deterred them from enrolling. Thus, given the limited yield (at best) and overt disruption (at worst) of the diagnostic interview, we dropped it from our protocol. Fortunately, the data were never intended to be primary, and we could still characterize our sample with the TOP data (our primary match and outcome measure). Further, the diagnostic assessments were not included in PsycBC's standard intake process (as they were with our former clinical partner). Thus, using them actually rendered our study less naturalistic vis-à-vis the system that we were trying to affect/improve with our intervention.

- PsycBC hired a full-time employee whose sole job description was to recruit patients to the trial.

- Our PsycBC collaborator, Tom Swales, who holds a significant amount of regional credibility, agreed to liaise with community physicians to market the study, which they could then mention to their patients prior to them contacting PsycBC. We suspected that the more patients were in the know about the project prior to calling or arriving for care, the more likely they would agree to take part vs. view it as an unexpected inconvenience.

- We posted a special announcement about the study on PsycBC's website, with the idea that it might predispose patients to participate if they read about the potential personal benefits before the intake call.

- We raised the upper age limit of study-eligible patients to 70 instead of 65. The literature does not demarcate older adulthood at 65, so we felt that raising the age would have no untoward effect on response to treatment.

- We continued to monitor PsycBC therapists who were not enrolled in the study, but now had the requisite number of baseline cases with TOP data for which we could establish a baseline report card. This would allow us to recruit from this pool if there was employment turnover from study-enrolled clinicians, or if other strategic needs arose (e.g., if having more therapists at a particular site could also positively affect patient recruitment and retention).

- The project's milestone schedule was unrevised for this contract modification.

For this modification, the only *major* changes to the protocol included the recruitment incentive and increase in the upper patient age limit, which our funder, PCORI, had already suggested and verbally approved in March 2018. Thus, at that time, we submitted the following 2nd (and minor) revision of our study protocol to the UMass IRB, which was approved in March

2018. This was the final protocol in place for the remainder, and majority, of the study. (Note that the protocol still references the diagnostic interviewing component, as that study element was not jettisoned until September 2018, as per the contract modification details noted above.)

PROTOCOL
APPLICATION FORM
SOCIAL, BEHAVIORAL, AND EDUCATIONAL FULL BOARD
HUMAN SUBJECTS IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL RESEARCH

University of Massachusetts Amherst (UMass)
Institutional Review Board (IRB)

Protocol ID: 2016-3401
Title: Enhancing Mental Health Care

Revision Form
1. Summarize the proposed changes to the protocol in lay terms (including details of ALL changes proposed AND modify all relevant protocol sections and attachments accordingly).
By way of a brief reminder, subjects in the current study include two mental health care stakeholder groups: (1) therapists affiliated with Psychological and Behavioral Health Consultants (PsycBC) who are providing outpatient psychotherapy, and (2) adult patients receiving psychotherapy (for varied mental health complaints) from the participating PsycBC therapists. PsycBC is a formal subcontract to UMass on this project, and their role on this project is restricted to providing the research team access to these two subject populations, and assisting the team in recruitment. Thus, PsycBC is not engaged in human subjects' research. The amendment proposed here deals solely with patient recruitment procedures. There are no changes to the research protocol itself.

Specifically, we are behind in our recruitment milestones, and our funder, PCORI, has asked us to consider strategies for increasing recruitment. In response, and internal to their business, PsycBC has provided additional resources to help boost recruitment. For example, they have devoted more intake staff to accept calls and to pitch the study via our verbal recruitment scripts. We initially rolled out the recruitment via just one of several intake call lines in order to work closely with just one PsycBC staff member. This, however, limited the number of potential patients to be recruited during a given day; opening up multiple lines for recruitment should help increase our numbers. PsycBC has also implemented a financial bonus for the intake worker who successfully recruits the most patients. We appreciate PsycBC's active role in attempting to bump recruitment; however, our PCORI Program Officer is concerned that these internal resources changes might not be sufficient on their own. Hence the present proposed amendment.

For context, at present, more PsycBC patients than we anticipated simply decline to learn more about the study during their initial intake call, presumably because they are eager to be

assigned to a clinician immediately on that initial call vs. going to a website to read about the study, to consent, to complete baseline measures, and then to return to a second intake call to be assigned to their clinician. Although we have successfully recruited 40 patients at present, with data to support that people are generally willing to participate if they agree to access the study information/consent form, we need to increase the number of people agreeing to access our online study consent form in order to catch up to our recruitment milestone projections (currently set at 66 patients recruited by March 1, and 112 by April 15).

The proposed strategy, which was recommended by our Program Officer, is to provide a monetary incentive for patients to agree to review our study materials online vs. declining outright on the initial intake call. PCORI has worked with research teams in the past who have used this strategy to successful effect, and they are willing to help us re-work our budget if the IRB approves this recruitment incentive. Our rationale is that a small monetary incentive may have a big impact in getting people to agree to pause momentarily their intake process to learn about, and consent to, our study (as noted, once patients get to the consent form, they often agree to participate). Given that reading the consent form takes several minutes, and that the person has to be willing to have their intake process span two different calls (which can delay by minutes to hours their assignment to a PsycBC therapist), we think that it is reasonable to compensate potential participants $15 for this time added to the intake process. As noted, because this money is tied to recruitment only, not participation, it is squarely a recruitment incentive, not a participant compensation/payment (for which a compensation schedule already exists in the current protocol). Although PCORI originally suggested offering $25, as did our DSMB and Advisory Board when consulting them about our recruitment issue, we feel that this might end up being a disincentive to actually participate (i.e., a person may be content with earning $25 simply to read a consent form, but then say “no thanks” to participating). Instead, we think that offering enough to be an incentive, but an amount that is more proportional to the time ask and to the compensation being offered for engaging in the full study protocol (i.e., $50), is likely to be more effective.

In sum, we are asking for approval to offer a $15 recruitment incentive to access our study consent form. We are also increasing the upper age limit of patients from 65-70. As the literature does not demarcate older adulthood at 65, this change is very minor, but *might* allow us to recruit a few extra patients who are interested in participating. There are no new attachments or other revisions to the study protocol language for this proposed amendment, and this recruitment incentive incurs no additional risk to potential participants.

2. Indicate Level of Risk involved with the changes proposed.
No change.

3. Describe any Other Changes.
As our funder is eager to learn if we can implement this recruitment incentive, I can be available to talk during your meeting on 3/7 if questions arise. My cell phone is 413-320-5752. Thank you!

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Title: Professor
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Human Subjects Training Completed? yes

Subject Populations(s) Checklist	**Yes/No**
Minors (under 18)	N
Pregnant Women	N
Cognitively Impaired or Decisionally Challenged	N
Older individuals (75 and over)	N
Healthy Volunteers	N
Students/Employees	N
International Populations	N
Prisoners	N
Other (i.e., any population that is not specified above)	Y

Other: Subjects will include two mental health care stakeholder groups: (1) therapists affiliated with PsycBC who are providing outpatient psychotherapy, and (2) adult patients receiving psychotherapy for varied mental health complaints from the participating therapists. PsycBC, a formal subcontract to UMass on this project, is an innovative health care organization and one of the largest providers of outpatient mental healthcare services in Ohio. PsycBC's role on this project is restricted to providing the research team access to these two subject populations, and assisting the team in recruitment. Thus, PsycBC is not engaged in human subjects' research.

Study Location(s) Checklist	**Yes/No**
University of Massachusetts Amherst	Y
Baystate Medical	N
University Health Services	N
Hartford Hospital	N
Other (Specify other Study Locations)	Y

Other: All study operations will be coordinated through Dr. Michael Constantino's (PI) Psychotherapy Research Lab at UMass Amherst. Subject data will be collected through our clinical partner, PsycBC, which employs a large team of psychiatrists, advanced practice nurses, psychologists, clinical counselors, and social workers serving children, adolescents, adults, and families in locations throughout Ohio and northern Kentucky. PsycBC's experienced specialists provide therapy for a wide range of mental health issues. PsycBC includes multiple treatment sites in Ohio that will contribute to data collection.

General Checklist	Yes/No
Training Grant?	N
Funded Study (or proposal submitted to sponsor)?	Y
Cooperating Institution(s)?	Y
Federally Sponsored Project?	Y
Human blood, cells, tissues, or body fluids (tissues)?	N
Subjects will be paid for participations?	Y

Cooperating Institution(s): (1) University at Albany, SUNY (Dr. James Boswell; Co-PI and subcontract); (2) Outcome Referrals Institute, Inc. (ORI; Dr. David Kraus; Co-PI and subcontract); and (3) PsycBC (Dr. Tom Swales; subcontract director). Note: At the time of this revision, an IAA has already been established for the approved original protocol with SUNY Albany and ORI. After consulting with UMass IRB staff, it is now clear that our new subcontract, PsycBC, is not engaged in human subjects' research; thus, no IAA is required/requested.

Funding Checklist
Grants/Contracts:

Funding Administered By: UNIVERSITY
PGCA#: 1503-28753
GAID#:
Funded By: Patient-Centered Outcomes Research Institute
1828 L Street, NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700 | Fax: (202) 355-9558
info@pcori.org
Principle Investigator: Michael J. Constantino
Grant/Contract Title: Enhancing Mental Health Care by Scientifically Matching Patients to Providers' Strengths

Are the contents of this protocol the same as described in grant/contract proposal? Y
Is this a training grant? N
Are any subcontracts issues under this grant? Y

Fellowships – None
Gift Funding – None
Dept. Funding – None
Other Funding – None

1. Purpose of the study

a. Provide a brief lay summary of the purpose of the study.

Research has shown that mental health care (MHC) providers differ significantly in their ability to help patients. In addition, providers demonstrate different patterns of effectiveness across symptom and functioning domains. For example, some providers are reliably effective in treating numerous patients and problem domains, others are reliably effective in some domains (e.g., depression, substance abuse) yet appear to struggle in others (e.g., anxiety, social functioning), and some are reliably ineffective, or even harmful, across patients and domains. Knowledge of these provider differences is based largely on patient-reported outcomes collected in routine MHC settings.

Unfortunately, provider performance information is not systematically used to refer or assign a particular patient to a scientifically based best-matched provider. MHC systems continue to rely on random or purely pragmatic case assignment and referral, which significantly "waters down" the odds of a patient being assigned/referred to a high performing provider in the patient's area(s) of need, and increases the risk of being assigned/referred to a provider who may have a track record of ineffectiveness. This research aims to solve the existing non-patient-centered provider-matching problem.

Specifically, we aim to demonstrate the comparative effectiveness of a scientifically-based patient-provider match system compared to status quo pragmatic case assignment. We expect in the scientific match group significantly better treatment outcomes (e.g., symptoms, quality of life) and higher patient satisfaction with treatment. We also expect to demonstrate feasibility of implementing a scientific match process in a community MHC system and broad dissemination of the easily replicated scientific match technology in diverse health care settings. The importance of this work for patients cannot be understated. Far too many patients struggle to find the right provider, which unnecessarily prolongs suffering and promotes health care system inefficiency. A scientific match system based on routine outcome data uses patient-generated information to direct this patient to this provider in this setting. In addition, when based on multidimensional assessment, it allows a wide variety of patient-centered outcomes to be represented (e.g., symptom domains, functioning domains, quality of life).

b. What does the Investigator(s) hope to learn from the study?

The goal of this project is to test the effectiveness of an innovative, scientifically-informed patient-therapist referral match algorithm based on MHC provider outcome data. We will employ a randomized controlled trial (RCT) to compare the match algorithm with commonplace pragmatic referral matching (based on provider availability, convenience, or self-reported specialty). Psychosocial treatment will remain naturalistically administered by varied providers (e.g., psychologists, social workers) to patients with mental health concerns. We hypothesize that the scientific match group will outperform the pragmatic match group in decreasing patient symptoms and treatment dropout, and in promoting patient functional outcomes,

perceived treatment credibility, outcome expectation, and care satisfaction, as well as therapeutic alliance quality. Doing so will establish the match algorithm as a mechanism of effective patient-centered MHC, and will suggest that this scientifically derived patient-provider matching intervention can be integrated into MHC systems to aid in treatment decision making, as well as increase personalization.

2. Study Procedures

a. Describe all study procedures.

We will compare the efficacy of naturalistic treatment either with or without the aid of scientific matching to a provider with a double-blind RCT. The project will involve two main phases. First, we will access a naturalistic baseline assessment of consenting PsycBC therapists' performance to determine their relative strengths and weaknesses in treating the problem domains measured by a multidimensional outcome tool. This period will establish our therapist sample pool and inform the RCT match manipulation (a match will represent a patient being assigned to a therapist who has empirically demonstrated during the baseline phase that he or she is stably effective at treating patients with the same type of presenting complaint).

Second, and after the baseline period, new consenting outpatients will be randomly assigned to the match (experimental) or no match (control) condition. The PsycBC administrators and their project-specific coordinator will collaborate with the research team to apply the randomization protocol. Treatment outcome will be assessed through the patient's actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after the point of termination on a randomly selected subsample). Outside of being matched to a therapist from a short-list of providers who have demonstrated (during the phase 1 baseline) reliable success in treating the patient's primary problem area, and completing study-specific measures for which participants will receive monetary compensation, treatment will be delivered as usual (the short list still allows for pragmatic considerations like availability and administrator assignment options).

Additional methodological details by study phase follow.

<u>Phase 1:</u> The most significant revision to the research protocol is that we no longer need to recruit/enroll patients for phase 1. Rather, phase 1 now focuses solely on PsycBC clinicians as our research participants. To inform the match condition, we will first establish the baseline track record of participating therapists' performance (across a minimum of 15 adult psychotherapy cases each) to determine their strengths in treating behavioral health domains measured by the primary outcome measure on which the match algorithm is based – the Treatment Outcome Package (TOP; Kraus, Seligman, & Jordan, 2005), which is described below in the listing of

relevant phase 1 attachments to this protocol. Developed and processed by our Co-PI (Dr. Kraus) and his subcontractor company, Outcome Referrals, Inc. (ORI), the TO is administered routinely as a core element of the PsycBC care model. That is, PsycBC already has an executed business agreement with ORI to have their patients complete the TOP as part of their standard clinical routine. Thus, we can leverage the existing PsycBC infrastructure to support the present study with little to no extra burden on administrators, providers, and patients. Moreover, although patient data are part of this baseline phase, they are protected within the business agreement between ORI and PsycBC, and the agreement allows for these coded data to be used to establish therapists' performance "report cards." So, to reiterate, patient TOP data are collected as part of standard operating procedure for PsycBC. At this stage, we are not collecting these patient data as a research protocol; rather, these coded patient data points (i.e., clinical care data points) inform our match intervention (by establishing therapist performance report cards across at least 15 cases) that is at the heart of phase 2 (described below). In phase 1, we are only actively recruiting provider participants; thus, no patient protected health information (PHI) is transmitted to the research team.

Importantly, at the time of this proposed IRB revision, most PsycBC clinicians who will choose to participate in the study will already have baseline data on the minimum 15 adult cases (through the patient's actual termination point or 16 weeks, whichever comes sooner) to establish their track record. In these cases, we simply need to enroll the therapist in the study (as discussed next). For therapists who wish to participate, but have yet to accumulate baseline performance data on the minimum 15 cases, we will track their performance (as per the TOP) on new, consecutive referrals until 15 total cases have been established for which the patient has either terminated or has been seen for at least 16 weeks. Few therapists will fall in this second category, and even if they do, they will generally only need a few cases to reach 15. Thus, we expect no issues completing the phase 1 performance baseline and finalizing the match algorithm for the phase 2 RCT by the established contractual milestone of 10/1/17.

Our minimum target therapist sample is 44 PsycBC providers (all of whom will be over the age of 18 themselves, and treating patients within the age range of 18-65). Therapists will be psychologists, clinical counselors, and social workers. Recruitment will be coordinated among our UMass-employed project coordinator (PC), the PsycBC-employed PC, clinic staff members, and the Co-PIs. Specifically, the PsycBC team will verbally present information about the study (both phases 1 and 2) to their providers during staff meetings. Alternatively, this information can be presented through email. At this preliminary recruitment stage, this information will be used to heighten awareness about the study and to garner interest in participating. (The verbal script for staff meetings and the email text are included as phase 1 attachments to this protocol.) The PsycBC PC will then provide the UMass PC (via

email) the names of providers who expressed interest in learning more about the study.

The UMass PC will subsequently contact interested therapist participants via email or teleconference (whichever is more convenient for the provider) to provide more study details/procedures and to direct the provider to an online consent form and survey. Providers remaining interested will access the secure study website to provide formal consent and to complete the baseline survey to which they will be directed after consenting. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the assessments in which their study patients will engage in both phase 1 (which is standard practice) and phase 2 (though they will not have access to the phase 2 research data at any time). Therapists will also need to consent to completing the aforementioned baseline survey prior to phase 1, as well as a few study-specific measures for each patient during the phase 2 RCT (the baseline survey and the phase 2 attachments are described in the relevant sections below and are included as phase 1 and 2 attachments, respectively, to this protocol). Relevant to phase 1, therapists will be compensated with a $20 Amazon gift card for the one-time completion of the online baseline survey, which will take no longer than 25 minutes to complete. Non-consenting therapists will receive case assignments as per standard care protocol and will simply not be included in the study (though we will analyze consenting and non-consenting therapists on demographic differences to see if any systematic sample bias exists).

Once therapists are enrolled in the study, the research team will access their naturalistically-collected TOP data to establish their performance across the minimum 15 cases to determine their personal strengths in treating patients across the risk-adjusted mental health problem domains measured by the TOP (recall that nothing changes in the therapist's service operation during this phase and, in fact, most of these TOP data points will have already been processed through ORI for cases seen by the providers in the past). Specifically, to establish therapists' performance track records, we will draw on each relevant patient's coded TOP data from baseline, week 8, and their termination point or week 16, whichever comes sooner (to mimic the definition of treatment outcome in the RCT phase discussed below). To reiterate, the research team is not formally enrolling patients into phase 1 of the study; rather, their coded data are simply processed by ORI, through its business agreement with PsycBC and its subcontractor role in the current project, to inform participating therapist report cards and the match algorithm).

Note that enrolled therapists will have an already-established TOP ID. This will allow the research team to link therapists? baseline survey data to their RCT data (i.e.,

responses to their own measures and their participating patients' measures) without use of any identifying information. As per customary precautions described below, a key that links therapist names and contract information with their data code will be kept in a separate, secure file that only trained research personnel can access.

Relevant phase 1 attachments to this protocol:

(1) Therapist recruitment materials: verbal script; email
(2) Therapist consent form and baseline phase 1 survey measures:

Provider Characteristics Form (PCF). This measure was developed by the research team to assess therapist demographic information, clinical experience, degree type, percent time seeing various patient types/diagnoses, any specialty training they have received, and dimensional ratings of the influence of various theoretical orientations on their treatment approach.

Therapist Perceived Strengths (TPS). This measure was developed by the research team to assess therapists' beliefs about their effectiveness in treating the various TOP domains when uninformed of their data-driven TOP track record. This measure will allow us to examine how accurate therapists are in perceiving their own strengths and weaknesses.

Phase 2: At this phase, the RCT will commence. The therapists will have already consented prior to phase 1 to be involved in the entire study, and they will know that patient data from their naturalistic baseline cases will have been used to create a personalized performance report card that will inform a prospective match with new patients they will treat in the trial. The therapists themselves will not see their report cards (as they will have been informed at the time of consent); rather, this information will be used by the research team with regard to the match manipulation.

Phase 2 marks the beginning of *patient* recruitment into the RCT. The patient population will be adult men and women (age 18-70) in PsycBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition based on TOP-derived presenting problem and to complete supplemental assessments (for monetary compensation, as per below) at baseline, at regular intervals during treatment, and at posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PsycBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, and poor quality of life. The only study-related patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical*

Manual of Mental Disorders (5th ed.; *DSM-5*[48]) diagnoses. Our minimum study target sample size is 264 patients (6 per therapist).

We do not anticipate problems meeting our recruitment numbers in the project time frame, as PsycBC schedules approximately 950 new patients per month. Moreover, their care model already uses the TOP to screen patients for appropriate level of care, and, as a formal subcontract on the project, they are willing to use a patient-level-best-matched clinician list that is generated in real time (based on the predictive validity of our match algorithm). Including the randomization protocol into the treatment delivery model will not create any systemic barriers.

Patients will flow into PsycBC via electronic or self-referrals. At initial contact, the PsycBC PC will ask patients for permission to be contacted by study personnel (i.e., the UMass PC) if they are interested in learning more about participation (this verbal script remains included as a phase 2 attachment to this protocol). If they are, they will be asked by the PsycBC PC to sign an authorization agreement (included in the phase 2 consent form) to allow their contact information (name, email address, and phone number) to be shared with the research team. The PsycBC PC's role is restricted to this recruitment task and administration of authorization to release the limited PHI; thus, no PsycBC personnel will be engaged in human subjects' research.

The PsycBC PC will provide the UMass PC with a daily list of referrals who have provided signed authorization to be contacted about the study. The UMass PC will then contact eligible patients to schedule a baseline consent/assessment. If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a teleconference diagnostic interview via a secure platform with a trained graduate clinical psychology research assistant (RA). During this session, the RA will first review the study details/procedures and respond to any questions. Patients will be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience (via an exit interview). They will also be told that although their participation in the trial will largely mimic the same treatment that they would receive if they were not participating, they must consent to be randomized, complete extra study-specific measures (before, during, and after treatment), complete an audio-recorded diagnostic interview (before and after treatment), and accept assignment to a clinician who will deliver individual psychotherapy. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they request a transfer earlier, this will be treated as a dropout point for the sake of the trial.

If a patient consents to be enrolled, they will sign the consent form and complete a baseline survey of measures (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure

of global distress, a measure of existential isolation, and a measure of interpersonal problems, all described below in the listing of relevant phase 2 attachments to this protocol) through a secure online platform linked to their typical TOP administration. Next, the trained research assistant (RA) will administer (on the same individual teleconference) the *M.I.N.I. 7.0.2 International Neuropsychiatric Interview* (described below in the listing of relevant phase 2 attachments to this protocol). Following PsycBC's standard intake process and this research-focused baseline consent/assessment session, patients will be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match). For their involvement in the additional diagnostic assessments and the additional measures that they will complete during the active treatment phase, patients will be compensated with a $50 Amazon gift card (on a prorated schedule for any missed assessments).

After the full baseline assessment, patients will be randomly assigned to condition (scientifically informed matched vs. pragmatic match) with a participating PsycBC provider. The UMass PC will generate the randomization sequences using an online random generator. Within condition, patients will be assigned sequentially to the therapists until they reach their study quota of 6 patients. Patients in the match condition will be assigned to therapists who have a demonstrated strength (derived from the baseline period) in treating, at a minimum, the patient's highest self-reported distress domain on the TOP-CS. Beyond the minimal match on the most elevated TOP-CS domain, our match algorithm will attempt to match patients to therapists on as many TOP-CS dimensions as possible, ultimately providing PsycBC with at least several well-matched choices for assignment within the match condition. In order to preserve this level of choice, there will be natural variability in the number of well-matched domains (some patients matched only on the minimum 1 TOP-CS domain, others matched on 2 or more domains). The match variability across both conditions will allow us to measure degree of match dimensionally as a moderator variable of our main treatment effect. Therapists will also be unaware of their patient's treatment condition (double blind), and they will treat both matched and non-matched patients (i.e., they will be crossed over the two conditions to minimize administrative disruptions). In the low probability event that there is no therapist meeting minimal match criteria for a patient in the match condition, that patient will be removed from the primary study analyses (though will, of course, still be offered treatment-as-usual at the clinic) and replaced with the next patient where a match does exist. As described in our power analysis below, we are oversampling in order to account for these "dropouts," or removed data points.

In addition to the baseline assessments already described, patients will be assessed via online surveys at regular intervals during treatment (the secure ORI platform will email hyperlinks to these surveys with reminders to complete them at the appropriate time intervals; the UMass PC can also follow-up with phone calls if needed). These during-treatment assessments will include the TOP-CS and measures

of existential isolation and interpersonal problems at every odd-numbered week after the start of treatment, as well as global distress, therapeutic alliance quality, perceived treatment credibility, and outcome expectation after every even-numbered session (all measures of these constructs are described below in the listing of relevant phase 2 attachments to this protocol). During treatment, participating therapists will also be asked to complete their respective versions of the alliance and credibility/expectation measures (also at even-numbered weeks; the UMass PC will email hyperlinks to these online surveys with reminders to complete them at the appropriate time intervals; the PC will also follow-up with phone calls if needed). For completing these measures, therapists will be compensated $50 per patient (again in the form of Amazon gift cards). All data collection will be coordinated through ORI, for which patients and therapists are assigned unique codes. Through their business agreement, ORI has direct access to PBC medical records; thus, it can push the relevant measures and track patient/therapist progress throughout the study.

As reminder, in both conditions, the providers will deliver treatment naturalistically (i.e., with no manipulation or influence from the research team). For the sake of the RCT, "treatment outcome" will be considered the point at which treatment terminates, or 16 weeks, whichever comes sooner. After the 16th week, or the termination session if it comes sooner, patients will complete posttreatment measures: the TOP-CS and TOP-CM, a measure of treatment satisfaction, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems (all described below in the listing of relevant phase 2 attachments to this protocol). Therapists will also document the nature of termination (measure described below in the listing of relevant phase 2 attachments to this protocol). Also at posttreatment, as defined by the trial, patients will undergo a repeat diagnostic telephone assessment (i.e., an RA-administered M.I.N.I., as described above).

We will also conduct a follow-up outcome assessment at 1 year after the patient's own termination on a randomly-selected subsample of 40 patients. Patients can easily be tracked in coordination with ORI and PsycBC; further, patients will have provided consent for this follow-up contact (should they be randomly chosen for it). At this assessment point, patients will again complete online the TOP-CS and TOP-CM, the brief measure of global distress, the measure of existential isolation, and the measure of interpersonal problems.

Note that all self-report measures (for both patients and therapists) at all time-points will be completed on Wi-Fi-connected tablets, or on home computers, through ORI's secure web-based platform. The TOP has its own dedicated website and HIPAA-compliant, secure server, and all other study-specific measures will be integrated into the TOP administration process.

We predict that the scientific match group will outperform the no match group to a clinically significant degree on TOP outcomes, global symptomatology, and interpersonal problems. We also expect that the match group will be more effective in promoting alliance quality and fostering more positive patient perceptions of treatment credibility and outcome expectation, all of which are established correlates (and candidate mechanisms) of positive treatment outcomes. Finally, we expect there to be less patient dropout in the match condition, and higher patient treatment satisfaction. Secondarily, we will examine 4 potential moderators of the expected between-group treatment effects on the primary TOP outcomes: (a) patient race (as it may be that the match algorithm is particularly potent, and an important responsiveness tool, for historically understudied or underrepresented patients), (b) degree of match of therapist strengths to patient problems (rated dimensionally as a ratio given that therapists can be matched on more than just the minimum 1 domain, and the elimination of harmful matches for any distressed domain reported by the patient), (c) patient distress severity, and (d) complexity of patient presenting problem. Thus, we will test if matching is only, or particularly, effective under the conditions of a central patient characteristic, a multiple domain match, and/or for patients with the most severe or complex pathology. As noted, we will also assess therapists' self-perceived strengths on the TOP domains. We expect to replicate previous literature showing that therapists are poor judges of their own efficacy, tending to underestimate negative effects and overestimate positive effects with their patients (Lambert, 2011), which would further underscore the importance of a data-driven match process.

Finally, for a subsample of stakeholders, we will conduct post-trial exit interviews (*N*s = 5 patients, 5 therapists) to gather invaluable input on how to be responsive to the study findings in terms of dissemination, implementation, and policymaking, including the potential importance of integrating diagnosis, provider age, race, or gender into subsequent matching approaches. We will recruit stakeholders in order of completion until we reach our target *N*s (therapists can only be involved once they have treated all 6 of their study patients). There are no other inclusion/exclusion criteria for the exit interviews; we will simply stop asking if participants are interested once we have reached our target Ns. This is consistent with the study consent forms, which clearly state that interested participants may be selected to engage in the interview.

Fully reflecting stakeholder engagement, and to eliminate any biases or power dynamics introduced by the PIs or their research staff, Advisory Board members (with appropriate credentialing for working with human subjects) will conduct the individual interviews. The PIs (Constantino & Boswell) will train 3 Advisory Board members on qualitative interviewing, and each will administer 1-2 pilot interviews as part of the training, plus 5 study interviews. The interviews will be conducted and audiorecorded via a secure webconferencing service and will last approximately 45-60 minutes. Participants will be compensated with a $100 Amazon gift card for their

time. RAs will transcribe the interviews, removing any identifying patient information. These RAs will also conduct a qualitative analysis of these text-based data.

Relevant phase 2 attachments to this protocol:

(1) Patient phase 2 recruitment verbal script
(2) Patient phase 2 consent form and phase 2 baseline measures packet:

TOP-Consumer Registration Form (TOP-CR; Kraus et al., 2005). The TOP-CR will be used routinely during the phase 1 baseline (and the phase 2 RCT) to assess patient demographics. On this form, patients indicate their age, gender, ethnicity, marital status, income level, employment status, religious identification, education level, general health status, and medical and mental health treatment history.

TOP-Clinical Scales and Case Mix (TOP-CS & TOP-CM; Kraus et al., 2005). This is the primary measure in our study; it will be used to establish the therapist report cards during the baseline phase to inform the match manipulation in phase 2. It also tracks patient outcomes. The TOP-CS consists of 58 items assessing 12 symptom and functional (including strengths) domains (risk-adjusted for case mix variables assessed via 37 items on the companion TOP-CM, such as divorce, job loss, comorbidity): work functioning, sexual functioning, social conflict, depression, panic (somatic anxiety), psychosis, suicidal ideation, violence, mania, sleep, substance abuse, and quality of life. Global symptom severity is assessed by summing all items or by averaging the z-scores (i.e., standard deviation units relative to the general population mean) across each of the 12 clinical scales. Domain-specific symptom severity is quantified as the individual z-scores for each clinical scale using general population means and standard deviations for the conversion. The TOP-CS has been shown to have excellent factorial structure, as well as good test-retest reliability across all scales. It is sensitive to change while possessing limited floor and ceiling effects (Kraus et al., 2005). The TOP also has demonstrated good convergent validity with scales like the Beck Depression Inventory (Beck, Steer, & Brown, 1996) and the Brief Symptom Inventory (Derogatis, 1975).

Symptom Checklist-10 (SCL-10; Rosen, Drescher, Moos, & Gusman, 1999). To evaluate outcome with an index separate from the TOP (to test convergence and enhance the validity of any between condition effects), we will also assess global distress with the SCL-10, a 10-item, well-validated and widely used self-report inventory that assesses psychological wellbeing.

Existential Isolation Scale (EIS; Pinel et al., 2014). To assess this isolation subtype, participants will complete the EIS, a six-item scale that requires participants to rate the extent to which they agree with items such as “I often have the same reactions to things as other people around me do” (reverse-coded) and “Other people usually

do not understand my experiences" and "People often have the same 'take' or perspective on things that I do" (reverse-coded). Participants respond using a 7-point scale. The EIS has high internal consistency, and has been validated extensively (Pinel et al., 2014).

Inventory of Interpersonal Problems-32 (IIP-32; Horowitz, Alden, Wiggins, & Pincus, 2000). To assess interpersonal problems, participants will complete the 32-item circumplex version of the IIP. This widely used instrument reflects interpersonal inhibitions and excesses, with each item rated on a 5-point scale. Higher total scores indicate more interpersonal problems. The IIP-32 also has 8 subscales (Domineering, Vindictive, Intrusive, Cold, Socially Inhibited, Nonassertive, Overly Accommodating, and Self-Sacrificing) that comprise a circumplex of problematic interpersonal behavior around the main interpersonal dimensions of affiliation and control. Like the original measure (Horowitz, Rosenberg, Baer, Ureno, & Villansenor, 1988), the IIP-32 has evidenced good psychometric properties.

(3) RA administered diagnostic assessment (baseline and posttreatment):

M.I.N.I. 7.0.2 International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al., 2016). The M.I.N.I. is a brief, structured diagnostic interview for DSM-5 and International Classification of Diseases (ICD; World Health Organization, 2008) psychiatric disorder classification. With its administration time of approximately 15 minutes, the M.I.N.I. is the psychiatric interview of choice in clinical trials and epidemiological studies. Despite its brevity, its psychometric properties compare favorably to longer instruments like the *Structured Clinical Interview for DSM* (SCID; First, Spitzer, Gibbon, & Williams, 1996). As part of the diagnostic evaluation, the RAs will complete the *Clinical Global Impression* (CGI), a widely used observer-rated scale that includes a 0-7 judgment of illness severity for which higher scores indicate more extreme illness.

(4) Patient phase 2 during-treatment measures:

TOP-CS, SCL-10, EIS, IIP-32. All described previously.

Working Alliance Inventory-Short Form, patient version (WAI-SF-P; Tracey, & Kokotovic, 1989). The WAI is the most widely used alliance measure, assessing patient-therapist agreement on the goals and tasks of treatment, and the quality of their relational bond. This 12-item short form, assessing these dimensions from the patient's perspective, has demonstrated sound psychometric properties.

Credibility/Expectancy Scale, patient version (CEQ; Devilly & Borkovec, 2000). The CEQ is the most widely used and psychometrically sound measure of the patient's perceived logicalness of a given treatment and expectation for the personal efficacy of that treatment.

(5) Therapist phase 2 during-treatment measures:

Working Alliance Inventory-Short Form, therapist version (WAI-SF-T; Tracey & Kokotovic, 1989). This is the parallel version of the WAI-SF described above, though now as rated from the therapist's perspective.

Credibility/Expectancy Scale, therapist version (CEQ; Devilly & Borkovec, 2000). This is the parallel version of the CEQ described above, though now as rated from the therapist's perspective (i.e., the therapist's sense of how logical the patient sees the treatment and how optimistic the patient is about receiving benefit from it).

(6) Patient phase 2 posttreatment measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

TOP-Satisfaction with the Treatment Process (TOP-STP; Kraus et al., 2005). This 32-item measure assesses patient's satisfaction with their provider, the treatment they received, and the treatment milieu (e.g., staff, other patients, etc.).

(7) Therapist phase 2 posttreatment measure:

Nature of Termination Form (NTF). This measure was developed by the research team to assess the nature of patients' termination from the provider's open-ended perspective, as well as through a choice format of unilateral/patient-generated, unilateral/therapist-generated, or mutual. Therapists can also describe in an open-ended format any unusual or noteworthy circumstances that may have led to the termination of therapy with this client (e.g., transfer of client to another therapist).

(8) Patient phase 2 subsample follow-up measures:

TOP-CS, TOP-CM, SCL-10, EIS, IIP-32. All described previously.

(9) Stakeholder exit interview protocols (patient and therapist versions)

b. State if audio or video taping will occur. Describe what will become of the tapes after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the tapes.

For the baseline and posttreatment patient assessments during phase 2, RAs will administer via teleconference the semi-structured diagnostic interview (M.I.N.I.), which will be audiorecorded. This will allow a different RA to review the recording and to make independent diagnostic and symptom severity determinations. With these two sets of ratings, we can then calculate interrater reliability on baseline and posttreatment diagnosis.

Audio recordings from the baseline diagnostic assessments will be digitally stored through the secure web-conferencing service. All data will be encrypted and password protected. Only the necessary research team members will know the login and password information and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings. The RAs, of course, will have completed the mandatory ethics training in human subjects' research, data management, and HIPAA compliance. These RAs will be independent evaluators who will not have access to other therapist or patient data. The recordings themselves will not be labeled with any identifiable information. The PI will routinely monitor the collection and analysis of recorded data.

After the recordings have been assessed for diagnostic reliability, the files will be securely deleted by the sponsored project contract term date of 6/16/20. No audio data or identifiable text data stemming from the recordings will be presented at meetings or in published articles. Only the reliability coefficients will be disseminated with the results of the full trial.

c. State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in Section #11 (Attachments).
Although the protocol does not involve deception, it does involve incomplete disclosure in Phase 2 given that participants are not given all of the information about the study until debriefing. Thus, in the debriefing form, we now provide participants the opportunity to withdraw their data upon learning the full scope of the research.

3. Background

a. Describe past findings leading to the formulation of the study.
Research has consistently identified significant variability in skill and outcomes between therapists (Baldwin & Imel, 2013; Boswell et al., 2013; Westra, Constantino, Arkowitz, & Dozois, 2011), even when therapists utilize an empirically supported treatment (EST). In fact, differences between treatment providers account for a greater portion of treatment outcome variance than the specific interventions delivered in controlled trials (Krause, Lutz, & Saunders, 2007; Wampold & Imel, 2015). Thus, improvements in MHC can occur by identifying effective providers in addition to promoting ESTs (Kraus et al., 2007).

In the largest study to date on this topic, our team investigated therapists' naturalistic treatment outcomes over many different problem domains (e.g., depression, anxiety, substance use, mania, sleep) in a sample of 6,960 patients and nearly 700 providers (Kraus, Castonguay, Boswell, Nordberg, & Hayes, 2011). The majority of therapists demonstrated a differential pattern of effectiveness

depending on the problem domain, and therapist domain-specific effectiveness correlated poorly across domains suggesting that therapist competencies may be domain-specific, rather than reflecting a core attribute or general underlying therapeutic skill. Importantly, although some therapists demonstrated effectiveness over multiple problem domains, no therapists demonstrated reliable effectiveness across all domains. Further, a small, but notable 4% of the therapists did not demonstrate effective outcomes on any domain. These data suggest that in any population of therapists (payer network, hospital, or community mental health system), there is an opportunity for behavioral health to do what medicine did decades ago – encourage provider specialization. Virtually every clinician has an area where they are above average (82-96%; Kraus et al., 2011, 2016), and our research suggests that if they specialize to their unique skills, population-level outcomes (i.e., symptom reduction, behavior change, increased functionality) will improve dramatically. This would reflect a major, and likely highly impactful shift to current MHC systems.

However, patients and referrers are typically unaware of the unique track record ("report cards") of local-area providers, which represents a critical gap in knowledge transfer within the MHC system. Without systematically collecting and disseminating performance report cards, stakeholders (e.g., patients, therapists, administrators responsible for case assignment, primary care physicians) lack vital information on which to base MHC choices and referral decisions, and that can inform personalized treatment (Boswell, Constantino, Kraus, Bugatti, & Oswald, 2015). Conversely, there is potentially immense advantage to matching patients to providers based on scientific outcome data (Constantino, Boswell, Bernecker, & Castonguay, 2013).

Consistent with this notion, the Institute of Medicine (IOM) has made recommendations to: (a) customize care based on the patient's needs, (b) share knowledge, (c) engage in data-driven decision-making, (d) promote transparency (including information on performance and patient satisfaction; Kohn, Saxena, Levav, & Saraceno, 2004), and (e) use valid and reliable assessment instruments to assess progress and to aid decision-making. The IOM has also recommended that MHC patients be provided with information on the quality of practitioner care (e.g., provider report cards) and use this information when making treatment decisions. Importantly, we have survey data that point to MHC patients, therapists, and administrators endorsing such applied knowledge transfer as a high priority (Boswell et al., 2015). Provider track record report cards are meaningful data to the MHC patient population, as are the mental health benefits that could stem from being well matched to provider.

We have developed over the past 20 years an innovative, technology-based mechanism/intervention to deliver report cards and drive this match concept within a patient-centered MHC model (Kraus et al., 2011). Our longitudinal data suggest that our match algorithm, based on our multidimensional outcome tool (the TOP) is

efficacious for MHC outcomes. In addition to our study highlighted above (Kraus et al., 2011), a more recent prospective study of 59 therapists and 3,540 patients resulted in a between-treatment controlled Cohen's d effect size of .80 (Kraus et al., 2016). Each therapist's first 30 patients were used to classify a therapist's skills in the 12 domains of symptoms and functioning as either statistically above average, average, or below average. The best matching algorithm functioned as follows: for each new, successive patient, he or she was classified as well-matched if the risk of harm was eliminated (i.e., the therapist was not below average when treating any elevated domain) and the therapist was above average in treating the patient's three most out-of-the-norm domains (e.g., depression, suicidality, and panic). Poorly matched patients had below average outcomes, with small effect sizes (d = .30) Well-matched patients, by contrast, achieved very large pre- vs. posttreatment effect sizes of d = 1.19. These data lend strong support that the proposed comparative effective research (CER) will yield similar results (i.e., increased efficacy and reduced harm) in realigning the skills of a large population of therapists in one of the forerunner Accountable Care Organizations (our partner Atrius) when matching empirically derived therapist skills with patient need. The technology/intervention is well established, it has demonstrated efficacy, and awaits investigation in a well-powered RCT.

4. Subject Population

a. State how many subjects you propose to use and state the rationale for the proposed number.

For the primary 3-level hierarchical model assessing treatment condition effects at the patient level on linear change rates within patients, we used Raudenbush and Liu's (2001) formula as incorporated in the Optimal Design program to determine the minimum numbers of therapists and patients needed to detect a moderate effect of condition (standardized difference between change rates = .50). With a minimum of 6 measurements spaced over the maximum 16 treatment weeks and assuming 5 patients per therapist, an intra-class correlation of .15, and an alpha of .05, we will need a total of 44 therapists and 220 patients to achieve a power of .80 to detect moderate condition effects on linear change rates. Factoring a 20% dropout rate at the patient level, running our experiment on 264 patients (6 per therapist) should provide sufficient statistical power to detect group differences on our primary outcome variables.

To summarize, based on this power analysis, we will for phase 1 access a naturalistic baseline assessment of a minimum of 44 consenting therapists' performance across a minimum of 15 cases to determine their strengths in treating the risk-adjusted domains measured by the TOP. We will then recruit a minimum of 264 patients for the phase 2 trial, assigning patients to the same 44 therapists who participated in phase 1 (they will see 6 cases each during the trial).

b. Describe the subject population, including the age range, gender, ethnic background, and type of subjects (e.g. students, professors, subjects with learning disabilities, mental health disorders, etc.). Please incorporate specific inclusion/exclusion criteria (e.g. physical and psychological health, demographic information, or other unique characteristics).

Therapist participants: As noted, our target sample is 44 therapist participants (age *range* = 30-65 years) who will be social workers, psychologists, and licensed clinical counselors. Reflecting PsycBC's therapist pool demographics, we anticipate that our provider sample will break down as follows: approximately 70% will be female; 88% will be white/non-Hispanic, 3% Black, 2% Hispanic, 2% "Other/mixed," and 5% Asian. Based on these projections and our power analysis, our targeted/planned therapist enrollment is indicated in an attached Targeted/Planned Enrollment Table (Therapists).

Patient participants: Patient participants will be 264 adult men and women (age 18-70) in PsycBC's referral stream (largely Cleveland clinic and primary care [PCP] practice). Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation) at baseline, at regular intervals during treatment, and at posttreatment. As this is an effectiveness design with a premium on ecological validity and scalability, virtually all patients in the PsycBC network will be eligible. It is most likely that the sample will be predominated by the following problem domains: depression, panic, substance abuse, and poor quality of life. The only study-related, patient-level exclusion criterion will be patients who are not the primary, informed decision-maker for their care. Thus, patients will present with a multitude of presenting problems across a spectrum of *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*) diagnoses. The composition of our sample will roughly match the average utilization data for age, gender, and race/ethnicity at PsycBC. Based on these projections and our power analysis, our targeted/planned patient enrollment is attached in an Estimated Final Racial/Ethnic and Gender Enrollment Table (Patients).

c. State the number and rationale for involvement of potentially vulnerable subjects to be entered into the study, including minors, pregnant women, prisoners, economically and educationally disadvantaged, decisionally challenged, and homeless people.

We are not specifically targeting these specific vulnerable populations, and our research design and/or the PsycBC care system will specifically exclude minors and prisoners. However, given the effectiveness design focused on maximizing ecological validity, some of our patients are sure to have economic and educational vulnerabilities, which are risk factors for mental health issues. Some women might also be pregnant.

d. If women, minorities, or minors are not included, a clear compelling rationale must be provided.
Minors will be excluded because they are typically not solely responsible for their own treatment decisions, and the outcome measure used in this study, and on which the match manipulation is based, focuses on adults.

e. State the number, if any, of subjects who are laboratory personnel, employees, and/or students. They should be presented with the same written informed consent. If compensation is allowed, they should also receive it.
N/A

f. State the number, if any, of subjects who are involved in research conducted abroad and describe any unique cultural, economic or political conditions.
N/A

g. Describe your procedures for recruiting subjects, including how potential subjects will be identified for recruitment. Attach advertisements, flyers, etc. in Section #11 (Attachments). Note: Potential subjects may not be contacted before IRB approval.
Therapist participants:

Recruitment will be coordinated among our UMass-employed PC, the PsycBC-employed PC, clinic staff members, and the Co-PIs, and will involve presenting information about the study (both phases 1 and 2) to providers through verbal script at staff meetings or by email. At this preliminary recruitment stage, this information will be used to heighten awareness about the study and to garner interest in participating. The PsycBC PC will then provide the UMass PC (via email) the names of providers who expressed interest in learning more about the study. The UMass PC will subsequently contact interested therapist participants via email or teleconference (whichever is more convenient for the provider) to provide more study details/procedures and to direct the provider to an online consent form and survey. Providers remaining interested will access the secure study website to provide formal consent and to complete the baseline survey to which they will be directed after consenting. Therapists will be told that the study is examining various referral processes that will not affect their delivery of treatment-as-usual. They will be informed that they will be blind to the specific nature of the referral manipulation in phase 2, but will be fully debriefed following the entire study and offered an opportunity to provide feedback on their experience. Therapists will also be informed of the assessments in which their study patients will engage in both phase 1 (which is standard practice) and phase 2 (though they will not have access to the phase 2 research data at any time). Therapists will also need to consent to completing the aforementioned baseline survey prior to phase 1, as well as a few study-specific measures for each patient during the phase 2 RCT.

Patient participants:

Phase 2 marks the beginning of *patient* recruitment into the RCT. Recruitment to the study simply means a willingness to be randomized to condition and to complete supplemental assessments (for monetary compensation). Patients will flow into PsycBC via electronic or self-referrals. At initial contact, the PsycBC PC will ask patients for permission to be contacted by study personnel (i.e., the UMass PC) if they are interested in learning more about participation. If they are, they will be asked by the PsycBC PC to sign an authorization agreement (included in the consent form) to allow their contact information to be shared with the research team. The PsycBC PC's role is restricted to this recruitment task and administration of authorization to release the limited PHI; thus, no PsycBC personnel will be engaged in human subjects' research.

The PsycBC PC will provide the UMass PC with a daily list of referrals who have provided signed authorization to be contacted about the study. The UMass PC will then contact eligible patients to schedule a baseline consent/assessment. If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a teleconference diagnostic interview via a secure platform with a trained graduate clinical psychology research assistant (RA). During this session, the RA will first review the study details/procedures and respond to any questions. Patients will be told that the study is examining various referral processes that will not affect their treatment; they will be kept unaware of the specific nature of the referral manipulation, but will be told that they will be fully debriefed following the study and offered an opportunity to provide feedback on their experience (via an exit interview). They will also be told that although their participation in the trial will largely mimic the same treatment that they would receive if they were not participating, they must consent to be randomized, complete extra study-specific measures (before, during, and after treatment), complete an audio-recorded diagnostic interview (before and after treatment), and accept assignment to a clinician who will deliver individual psychotherapy. Patients will also be asked to remain with the same therapist through at least 16 weeks of treatment; however, if they request a transfer earlier, this will be treated as a dropout point for the sake of the trial. If the patient consents to be enrolled, they will sign the consent form and complete a baseline survey of measures (i.e., the TOP-CR, TOP-CS, and TOP-CM, a brief measure of global distress, a measure of existential isolation, and a measure of interpersonal problems) through a secure online platform linked to their typical TOP administration. Next, the trained RA will administer (on the same individual teleconference) the M.I.N.I. Following PsycBC's standard intake process and this research-focused baseline consent/assessment session, patients will be randomized to condition and assigned to a provider based on the experimental parameters of that condition (i.e., scientific match vs. pragmatic match).

h. Compensation. Explain the amount and type of compensation (payment, experimental credit, gift card, etc.), if any, that will be given for participation in the study. Include a schedule for compensation and provisions for prorating.
Therapist participants:

Therapists will complete, in no longer than 25 minutes, a few study-specific measures as part of a phase 1 baseline survey for which they will be compensated $20 in total (in the form of an Amazon gift card).

During Phase 2, therapists will also complete a few study-specific measures throughout treatment with each of the 6 participating patients treated during the phase 2 RCT; they will be compensated $50 per patient for this additional, but minimal, time burden. The compensation will again be in the form of an Amazon gift card.

If therapists complete their measurement schedule through all possible contact points for a given participating patient (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination for a participating patient that occurs prior to week 16 of treatment, they will receive full compensation (i.e., a $50 gift card for that patient).

However, if a therapist withdraws from the study, they will have the option to be compensated on a prorated basis for the measures that they have already completed regarding each of their participating patients. This proration works out to approximately $3 per week for a participating patient, which will be deducted for the number of weeks “missing” from therapists’ assessment schedule (i.e., based on the point at which the therapist withdrew from the study). For example, if a therapist completes the measurement schedule for a given patient through week 8 (9 weeks, including baseline) and then withdraws from the study, they will have “missed” 8 weeks of data collection for that participating patient. Their compensation for this participating patient will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26. This adjustment will be completed for any and all relevant participating patients. To summarize, therapists who withdraw from the study will have the option either to (a) receive their relevant prorated compensation, or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the therapist participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Patient participants:

Patients in Phase 2 will undergo a semi-structured diagnostic interview at both baseline and posttreatment, as well as complete several study specific measures

throughout treatment (and, if randomly selected, at a follow up); they will be compensated $50 total for these non-routine aspects of their care. The compensation will be in the form of an Amazon gift card. If patients complete their measurement schedule through all possible contact points (i.e., baseline + 16 treatment weeks = 17 weeks), or complete their measurement schedule through a planned termination that occurs prior to week 16 of treatment, they will receive full compensation. However, if they drop out of treatment prior to week 16, and their end point was not a planned termination that can be considered posttreatment for the purpose of the study, compensation will occur on prorated schedule. This works out to approximately $3 per week, which will be deducted for the number of weeks "missing" from the schedule. For example, if a patient completes the measurement schedule through week 8 (9 weeks, including baseline), and they did not engage in a planned termination, they will have "missed" 8 weeks of data collection. Their compensation will be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26.

Patients who withdraw from the study (which is distinct from simply dropping out of treatment) will be given the option to (a) receive prorated compensation for the completion of measures up until the point of withdrawal (following the proration schedule outline above), or (b) to forgo prorated compensation in order to no longer be contacted by the research team.

If the patient participates in an exit interview, he or she will receive full compensation in the form of an additional $100 Amazon gift card.

Finally, note that in the event that a participant (either a patient or therapist) withdraws from the study during phase 2, the other dyad member (either the patients seen by a withdrawing therapist or the therapist treating a withdrawing patient) will not be penalized; that is, as long as they have already consented to the study, they will receive the full amount of reimbursement (i.e., a $50 gift card) regardless of the point at which their patient/therapist withdraws. However, note that consistent with the wishes of the participant, we will, of course, stop collecting data at the point of withdrawal (i.e., if therapists withdraw, we will stop collecting data from their patients who will be compensated fully; if patients withdraw, we will stop collecting data from their therapist regarding that patient and the therapist will be compensated fully for that patient).

i. **Please state: A: The total expected duration of the study, including the time expected for data analysis (e.g., This study is expected to last 1 year) AND B: How much time each subject is expected to be involved in the study (e.g., The involvement of each subject will be 1-session for a total of 90 minutes).**
A) The project is funded in the form a cost-reimbursement contract for which a specific milestone schedule exists. The contract start date is 9/15/16 and the contract term date is 6/15/20. All analyses will be completed by the term date. Details are available in the attached updated milestone schedule.

B) Therapist subjects will be involved for 2 months in phase 1, as well as through the phase 2 trial (approximately 2 years, though with variability depending on when they have been assigned and have treated their 6 study cases). Patients in phase 2 only will be involved in the study protocol through their actual termination point or 16 weeks, whichever comes sooner (we will also conduct a follow-up outcome assessment at 1 year after termination on a randomly-selected subsample of 40 patients).

5. Risks

HHS Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research..." This also includes risks to subject confidentiality and any discomforts, hazards, or inconveniences.

For the categories below, include a description of risks.

a. Describe the risks related to:
Physical well-being
None anticipated.

Psychological well-being
Regardless of condition, PsycBC will employ its usual triage assessments, therapists will employ their usual treatments, and patients will be receiving their usual care. Consequently, there are no risks from our research protocol over and above what would normally be expected in routine assessment and psychotherapy, and PsycBC has its usual clinical and safety protocols in place (and the clinical personnel to execute them).

In treatment, some individuals may experience emotional upset during sessions. Additionally, some participants may experience disappointment with their rate of progress or setbacks. The risk associated with such reactions will be addressed clinically by the therapists who are treating these issues and who have peer and administrative support. To reiterate, these treatment risks would occur in the course of treatment-as-usual. These are not additional risks stemming from the research protocol. Further, the TOP outcome monitoring system, which is at the center of our research project, is already being used by PsycBC providers without incident.

As is typical in psychological research, some of the assessment questions from the research measures may be experienced as intrusive and/or may cause anxiety. The risk from such increased anxiety, however, is mitigated by the use of skilled and extensively trained assessors who are aware that such reactions may be related to a person's presenting problems, or simply a function of the intimate and emotionally

intense nature of psychological services. In addition, the PIs, PCs, and/or PsycBC staff and administrators will be available to meet with any participant who may be unduly disturbed due to the few research tasks. Because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and email address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address (which they will request verbally, if necessary) for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

Economic well-being

Given that therapist performance data are being collected, it is reasonable to be concerned about possible employment implications were an employer (i.e., clinic administrator) to attempt to interpret study information incompletely (i.e., infer lack of therapist effectiveness to the point of questioning employability). This risk, however, is extremely minimal for the following reasons:

(1) As a condition of being involved in the study, clinic administrators will be required to agree that therapists' participation or non-participation in this research will in no way affect their standing/employment at their community mental health clinic.

(2) The research team will not reveal therapist performance data to clinic administrators or staff members; that is, the study could be considered "triple-blind." Neither patients nor therapists will know when they are in an experimentally-matched vs. typically-matched dyad, and administrators/staff members will not have access to the therapists' report cards.

(3) However, administrators and staff members are required to be in the know about well-matched therapist "short-lists," as this is essential to the research design; that is, when patients are randomized to a well-matched therapist, those potential therapists need to be identifiable. It is possible that administrators or staff members might misinterpret these data to suggest that a given therapist is ineffective (if he or she is never or rarely showing up on a shortlist). However, we will guard against this misinterpretation by educating administrators and staff members that the shortlist only represents, in a small cross-section of time, therapists that have been shown to be effective on at least 1 of 14 domains, which represents a given patient's most severe problem at that time (the match criterion). We will stress that this does not mean that a therapist is globally ineffective. It may just be that patients randomly assigned to the match group are tending not to have the types of problems for

which a given therapist is relatively effective. That therapist, though, could be highly effective at treating one or even many other domains.

(4) Finally, administrators and staff members will not be told which therapists are or are not participating in the study. Thus, lack of being on a shortlist, for all that they will know (unless a therapist openly reveals that he or she is participating in the study), could simply connote a choice to not participate in the project.

Social well-being
None anticipated.

Breach of confidentiality (including audio/video taping)
A breach of confidentiality represents a risk, but every step will be taken to minimize this risk. PsycBC and ORI routinely handle PHI and are in compliance with HIPAA regulations. Any "hard" materials (e.g., diagnostic assessment summaries) that are collected for research purposes only will be stored in a locked cabinet in the PI's Psychotherapy Research Lab. There will be no hard copy data collected at the PsycBC clinic sites. Most of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Finally, digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted

b. For research conducted internationally, describe any political or sociocultural considerations that may affect your research design (for example, in some communities it may not be customary to sign documents, etc.)
N/A

c. Discuss plans for ensuring necessary medical or professional intervention in the event of a distressed subject.
The Co-PIs, project coordinator, PsycBC staff members, and PsycBC administrators will monitor the treatments and data collection; thus, they can assist in regularly monitoring any adverse events. Such negative occurrences are unlikely to be trial-related, as all patients will be receiving treatment-as-usual. Therefore, any adverse event will be addressed with PsycBC's well-established procedures for monitoring services and managing treatment-related disturbances. Nevertheless, any adverse event will be recorded and immediately reported to the IRB (UMass), PCORI (funder), and the project's Data Safety and Monitoring Board (DSMB).

Should, during the course of the study, a patient show evidence of psychological or physical deterioration, the patient will be assessed comprehensively in the domains of concern (except in the case of a life-threatening physical emergency, such as the emergence of acute chest pain, in which case 9-1-1 will be called immediately). If the

therapist deems that the patient meets criteria for a psychiatric hold (e.g., patient is an imminent danger to self or others), the therapist will arrange for the patient to be brought to the emergency department and will contact his/her PsycBC administrator and the PI to debrief. If a patient is not meeting criteria for a psychiatric hold, but is showing clear signs of decreased mental status, the therapist will continue to meet with the patient, as well as - in consultation with the PsycBC administrator - make arrangements for the most appropriate level of care.

As noted, because the pre- and posttreatment diagnostic interviews will be conducted via telephone, the graduate RA (being trained as a clinician and supervised by their site PI, Dr. Constantino or Boswell, both of whom are licensed clinical psychologists and mental health care providers) will have the patient's contact information (phone number and email address) on hand. If the patient reveals clinically elevated suicidality or homicidality, the RA will contact 9-1-1 and report the patient's contact information and location address (which they will request verbally, if necessary) for emergency response. The RA, if applicable, will also execute any duty to warn to the best of their ability (in addition to contacting the local authorities).

6. Benefits

a. Describe the potential benefit(s) to be gained by the subjects or by the acquisition of important knowledge which may benefit future subjects, etc. (This DOES NOT include compensation or extra credit).

The most direct benefit a participant in this study may receive is the reduction of symptom-related distress and improved functioning. In addition, patients (especially those in the match condition) will receive more personalized MHC. Psychotherapists (especially those in the match condition) may experience a greater level of positive impact across their caseloads. Given that the actual treatments being provided will not be manipulated, the benefits of participation are judged to far outweigh the potential study-specific risks.

There is immense potential for future therapists and patients to benefit from the results of this study; if the hypotheses are supported, there will be cause for substantial revamping of MHC systems to capitalize on matching patients to therapists who have an empirically demonstrable track record of strength in treating patients with similar presenting problems.

7. Procedures to Maintain Confidentiality

a. Describe the procedures in place which protect the privacy of the subjects and maintain the confidentiality of the data, as required by the federal regulations, if applicable.

Multiple steps will be taken to protect confidentiality. As mentioned, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy data collected at the PsychBC sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Digital recordings of diagnostic assessments will be stored in a secure, password protected website. The recordings themselves will be encrypted.

Only designated study personnel will have access to identifiable, study specific, private information about human subjects. When registering on the TOP system, as required by PsychBC's standard operating procedures, both patients and therapists are assigned a random number code that links all subsequent assessments and is separated from identifiable information. This random number code will function as each participant's study code and will be used to link participants' data. As noted, all therapist and patient data (outside of diagnostic assessment summaries and the TOP administrations) will be collected through a web-based platform. The assigned participant code will be used to link/aggregate information, so private information will not be requested after the baseline assessment/consent process. Only the PI and essential research staff will have access to the list that links identifiable information with the participant's study code. Any audio recordings will be encrypted and password protected. Only the Co-PIs will know this password and have the capacity to access the recordings. When it is time to analyze the recordings for reliability coding, designated, trained RAs will also have access to the recordings; however, they will not have access to additional identifiable information (only the information required to complete the analysis). For any data used for research and publication purposes, the confidentiality of participant information will be ensured.

b. If information derived from the study will be provided to a government agency, or any other person or group, describe to whom the information will be given and the nature of the information.

The PI is required to submit information (i.e., contractual "deliverables") on a regular basis to PCORI (the study sponsor), including IRB protocols, interim progress reports, advisory board meeting minutes, engagement plan updates, evidence of diagnostic criterion reliability from training cases, interim data reports, presentation abstracts and documentation of acceptance, manuscript copies, letters of endorsement from scientific and consumer groups, final data analysis summary, and final research report. Details on deliverables are available in the aforementioned (and attached and updated) milestone schedule. No PHI will be transmitted to PCORI.

c. Specify where and under what conditions study data will be kept, how specimens will be labeled and stored (if applicable), who has access to the data and specimens, and what will be available to whom.

As noted, minimal paper forms (e.g., diagnostic summary forms) will be kept in a locked cabinet in the PI's locked Psychotherapy Research Lab. There will be no hard copy research-only data collected at the PsycBC sites. Virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. Digital recordings of diagnostic assessments will be stored in a password protected website, and securely deleted by the project contract's term date. Only the relevant members of the research team will have access to the participants' data and only the PI will have long-term access to identifiable information. As noted, all assessments will be linked with a participant code. Any records linking the code to the participant's name or voice recording will be kept in a separate locked file cabinet in the PI's office. These records will be destroyed 5 years after the contract term date.

8. Potential Conflict of Interest

a. Do any of the involved investigators or their immediate family (as described below) have consulting arrangements, management responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)? Y

b. Do any investigators or their immediate family have any financial relationship with the Sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment? N

c. Is any Investigator(s) a member of an advisory board with the Sponsoring company? N

d. Do any investigators receive gift funds from the Sponsoring company? N

e. Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol? Y

"Immediate family" means a spouse, dependent children as defined by the IRS, or a domestic partner. If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship. i.e., a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what institution(s) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. If you answer yes to any of the questions above, please go to the policies for more information.

9. Informed Consent

You can add different Consent Forms, Alteration Forms, and Waivers. Provide consent process background information, in the table below, for each Consent Form(s), Alteration Form(s), and Waiver(s).

9.1. Consent Form – therapist consent form revised

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
UMass personnel only: either the PC or an RA.

How is consent being obtained?
Therapists will meet or speak via teleconference with the UMass PC or an RA to learn about the study details/procedures and to provide formal consent through an online baseline survey to which they will be directed.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
The PI and his collaborators will provide close oversight of the entire protocol, including regular consultations with a study Advisory Board and the DSMB.

9.2. Consent Form – therapist exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a therapist agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the therapist will be directed. Coercion will be minimized by clearly stating that participation is voluntary.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
If the interviewer interacts with a therapist who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the interview protocol.

9.3. Consent Form – patient consent form revised

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
UMass personnel only: either the PC or an RA.

How is consent being obtained?
If a patient agrees to engage in a consent/baseline assessment session, the PC will schedule a telephone diagnostic interview with a trained graduate clinical psychology RA (employed at either UMass or University at Albany). The RAs will first review the study details/procedures and obtain consent through an online baseline survey to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will be an inclusion criterion for the study. Moreover, if a clinic staff member, the PC, or an RA interacts with a patient who appears to have competency issues in the decision-making process for engaging in the study, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the study. The DSMB will be consulted if appropriate.

9.4. Consent Form – patient exit interview supplemental consent form

Who is obtaining consent? The person obtaining consent must be knowledgeable about the study and authorized by the PI to consent human subjects.
The exit interviewer (i.e., RA or advisory board member).

How is consent being obtained?
If a patient agrees to engage in an exit interview, the interviewer will review the study details/procedures and obtain supplemental consent through an online link to which the patient will be directed. Coercion will be minimized by clearly stating that participation is voluntary and will in no way impact the patient's treatment.

What steps are you taking to determine that potential subjects are competent to participate in the decision-making process?
Competency for making one's own treatment decisions will have been an inclusion criterion for the main study. Moreover, if the interviewer interacts with a patient who appears to have competency issues in the decision-making process for engaging in the exit interview, they will immediate bring this concern to the PI or a Co-PI before enrolling them. The team will them make an informed decision as to whether to include that person in the interview protocol. The DSMB will be consulted if appropriate.

10. Assent Background

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

11. Attachments

Document Type	Document Name	Attached Date
Questionnaires	Patient Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	Therapist Phase 2 During-Treatment Measures Packet	10/04/2016
Questionnaires	TOP-STP	10/04/2016
Questionnaires	Stakeholder Exit Interview Protocols	10/04/2016
Federal Grant/Sub-contract	PCORI IHS-1503-28573_Constantino_executed contract	10/04/2016
Federal Grant/Sub-contract	PCORI Original Contract Proposal_all sections	10/04/2016
Other	Constantino Lab Personnel Link- Google Docs	10/04/2016
Other	PCORI_Phase 2_Patient Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Patient Data Collection Reminder Call Script	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Email Template	11/13/2016
Other	PCORI_Phase 2_Therapist Data Collection Reminder Call Script	11/13/2016
Questionnaires	MINI 7.0.2 Standard	11/13/2016
Advertisements	PCORI_Clinician Recruitment_Verbal Script_REVISED_clean	08/13/2017
Advertisements	PCORI_Clinician Recruitment_Email_REVISED_clean	08/13/2017
Advertisements	PCORI_Patient Recruitment_Verbal Script_REVISED_clean	08/13/2017
Questionnaires	PCORI_Clinician Consent & Baseline Measures Packet_REVISED	08/13/2017

Questionnaires	PCORI_Patient Consent & Baseline Measures Packet_REVISED	08/13/2017
Questionnaires	PCORI_Patient Posttreatment Measures Packet_REVISED w. debriefing form	08/13/2017
Questionnaires	PCORI_Clinician Posttreatment Measures Packet_REVISED w. debriefing form	08/13/2017
Questionnaires	TOP-CS & TOP-CM	08/13/2017
Other	PCORI_Targeted Enrollment Tables_REVISED_clean	08/13/2017
Other	PCORI Milestone Schedule_REVISED	08/13/2017
Other	Participant Flow_REVISED	08/13/2017
Other	Data Collection Schedule Revised	08/13/2017
Federal Grant/Sub-contract	Constantino_IHS1503-28573_Mod 001 SUB_FE 20170808_FINAL EXECUTED MOD	08/13/2017
Other	PCORI IRB Proposal_R1_for PsycBC_FINAL submitted	08/13/2017
Other	ORI-PBC_Business Associate Agreement	08/13/2017

Obligations

Obligations of the Principal Investigator are: Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes; Consent Forms - All subjects will be given a copy of the signed consent form. Investigators will be required to retain signed consent documents for six (6) years after close of the grant or three (3) years if unfunded; Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events - All adverse events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than ten (10) working days; Continuing Review – IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.” Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel; Adverse Events/Unanticipated Problems - All events occurring in the course of the protocol will be reported to the IRB as soon as possible, but not later than five

(5) working days; Continuing Review - IRB Protocol Report Forms will be submitted annually at least two weeks prior to expiration, six weeks for protocols that require full review; Completion Report - The IRB will be notified when the study is complete. To do this, complete the IRB Protocol Report Form and select “Final Report.”

The Principal Investigator has read and agrees to abide by the above obligations. Y

D. Summary of the 3rd formal modification to the PCORI contract (January 2018); no revision to the study protocol

CONTRACT MODIFICATION SUMMARY

On January 8, 2018, PCORI approved the 3rd contract modification (IHS-1503-28573 Modification 003), which included the following changes:

- We updated our patient enrollment target from 264 to 281 based on a more conservative attrition rate of 25% (up from our original, less conservative estimate of 20%). With this modification, enrolling 281 patients into the trial allowed us to meet our target of 211 usable case for final data analysis (281 * .75 = 211). Based on this adjustment, we also updated accordingly our *Estimated Final Racial/Ethnic and Gender Enrollment Table*.

- We updated our timeline and milestone schedule based on the PCORI-approved 6-month extension to the contract end date. This no-cost extension was precipitated by delays in patient recruitment, which we successfully addressed via our formal project remediation plan.

For this modification, there were no changes to the study protocol.

Online Survey Consent Form – Patients

Title of Research: "Enhancing Mental Health Care" Study
IRB Number: 2016-3401
Researcher: Michael J. Constantino, Ph.D.

Description of the Study

You are being asked to participate in this research study because you are an adult (age 18-70) who makes your own treatment decisions and will receive outpatient psychotherapy through a PsychBC therapist.

PsychBC is collaborating with researchers at the University of Massachusetts, University at Albany, and Outcome Referrals, Inc. on a study aimed at learning more about ways to improve mental health care. The study is being funded by the Patient-Centered Outcomes Research Institute (PCORI; IHS-1503-28673).

Your participation involves the following activities:

- After reading and signing this consent document, you will be directed to a brief survey, which will take no more than 30 minutes to complete. When done, you will speak with your intake worker who will randomly assign you to receive treatment from a PsychBC provider in one of two patient-provider match conditions that we are testing. Neither you nor your therapist will know the basis of the match, though you will be debriefed after treatment ends. Importantly, **outside of your assignment to therapist, your treatment will not be affected.** Your therapist (who has already agreed to participate in this study) will conduct treatment-as-usual with no influence from the research team. We will, though, ask for you to remain with the same therapist throughout your treatment, though you are certainly free to request a transfer if you prefer.

- Soon after your assignment to a therapist, a research team member will email you to orient you to the few remaining study procedures. During treatment, you will be asked to complete several study-specific measures online at regular intervals (the project coordinator will email links to these surveys with reminders to complete them at the appropriate times). These measures will take no more than 15 minutes to complete each time.

- After your treatment ends or at week 16, whichever comes sooner, you will again be asked to complete several study-specific measures online (taking no more than 15 minutes to complete).

- If you give consent, you can also be randomly selected to complete measures at 1 year following your final session. This will give us a sense of your longer-term mental health functioning.

- Finally, you can express interest in taking part in a separate brief exit telephone interview. If you are selected, the interview will involve answering a series of questions about how to be responsive to the study findings in terms of dissemination, implementation, and policymaking. This phone interview will take 45-60 minutes.

Your participation is completely voluntary and you can stop at any time. **Your responses will remain confidential, including from your therapist**. Also, your participation or non-participation in this research will in no way effect your standing or treatment at your community mental health clinic.

Benefits

You may experience a direct benefit from your participation in this study. Your consideration of the questionnaire items might provide additional insight into your functioning and how your therapy is going, or went.

Moreover, your information will help us test whether different patient-clinician match scenarios differentially affect patients' mental health symptom and functioning. Thus, society and future mental health treatment may benefit from your participation.

Risks and Protections

Your participation in this study is unlikely to involve significant risk. You will receive treatment-as-usual. The only differences are that you will (1) be randomly assigned to receive treatment from a PsychBC provider in one of several match conditions that we are testing, and (2) you will complete the measures discussed above that assess your mental health symptoms and functioning. The items may cause some slight emotional discomfort; however, this will not be over and above what you routinely discuss during your therapy sessions. The additional time that it will take to complete the study questionnaires may also be a slight inconvenience to you. However, you will be paid for your time according to the compensation schedule below.

Your responses to the measures will be protected, including from your therapist. However, if you endorse items that seem critical for your therapist to know, a clinic administrator may choose to inform the therapist of just these relevant responses. This could influence what you discuss in subsequent sessions, though it would be in the service of improving your care.

Risk of loss of private information/confidentiality is considered minimal given that relevant study information and online forms will be linked with a study code, rather than identifying information. Moreover, virtually all of the data collected in this study (including consent) will be through a secure, web-based platform using a tablet or computer. This method offers greater protection because it guards against human error and negates the need for long-term storage of paper forms. Summary documentation might take hard copy form, in which case the forms

would be stored in a locked cabinet in a locked psychotherapy research lab. These forms will be destroyed after the study is complete.

Assessment results can only be accessed by research personnel through a protected username and password. Only your name, phone number, and email address will be collected during the consent process to facilitate your payment for participation. You will be paid via email with Amazon.com gift cards, though your phone number will be a backup contact means should there be technical issues with email. Your contact information will not be connected to any other personal information, and it will be kept in a locked cabinet in a locked research office. All information obtained in this study is strictly confidential unless disclosure is required by law or deemed clinically necessary (as discussed above). In addition, the Institutional Review Board, the sponsor of the study (PCORI), and University or government officials responsible for monitoring this study may inspect these records. For any data used for research and publication purposes, the confidentiality of participant information will be ensured.

Your participation in this research is entirely voluntary. Even after you agree to participate in this research, you may decide to leave the study at any time without penalty or loss of benefits to which you may otherwise have been entitled. You should also be aware that the investigator may withdraw you from participation at his/her professional discretion.

Compensation

In exchange for your participation in the study through the full 16 weeks of treatment, or a planned termination prior to 16 weeks, you will be compensated in full with a $50.00 Amazon.com gift card. However, if you drop out of treatment prior to week 16, or your last session was not a planned termination, your compensation will be prorated. Specifically, we will deduct $3.00 per “missing” week of data collection. For example, if you complete the measurement schedule through week 8 (9 weeks, including baseline), and you did not engage in a planned termination, you will have “missed” 8 weeks of data collection. Your compensation would be adjusted as follows: $50 - $24 ($3 x 8 weeks) = $26.00. Note that you would also have the option to forgo this compensation if you no longer wished to be contacted by the research team in any way.

If you engage in the exit interview, you will be compensated an additional $100 Amazon.com gift card.

Potential Conflict of Interest Disclosure

Dr. David Kraus (a co-investigator) is a stockholder of Outcome Referrals, Inc. (a subcontractor to UMass on this grant). Dr. Kraus is also the inventor of the scientific referral patent (US Patent No. 7,873,525) that is being tested through this grant.

Contact Information

If you have questions about this project or if you have a research-related problem, you may contact the project coordinator, Felicia Romano (508-331-3905, fromano@umass.edu), or the principal researcher, Dr. Michael Constantino (413-545-1388; constanm@umass.edu).

If you want to contact someone not directly involved in this study, you can reach the psychology Department Chair through Laura Wildman-Hanlon (413-545-2378).

If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu.

Agreement to Participate

By clicking the first "I agree," you affirm that (1) you are at least 18 years of age, which is the minimum age to participate in this study, and (2) the purpose and nature of this research have been sufficiently explained, that you have read and understood this consent form, and that you agree to participate in this research study. You are free to withdraw at any time simply by closing this browser window (prior to submission of your responses). Please print a copy of this page for your records.

[I agree/I do not agree]

By clicking the second "I agree," you affirm that you will not discuss the contents of this study with anyone other than the researchers (unless you are harmed due to participation).

[I agree/I do not agree]

Patient Authorization to Release Information for Research

If you have consented to participate in the study, we also need written authorization to share limited information about you with the research team. Specifically, we ask for your name, preferred telephone number, and preferred email address. This will allow the research team to contact you about study procedures and to compensate you for your time.

You are in no way obligated to release this information. Your treatment at PsychBC will not be affected in any way whether you are or are not you engage in the study.

I have read and understood the present request, and I authorize PsychBC to share my contact information with the research staff. I understand that **no other protected health information will be shared with the research team prior to your consent to participate in the study.**

[I agree/I do not agree]

By clicking the second “I agree,” you authorize PsychBC to share the following contact information:

Name:
Preferred telephone number:
Preferred Email address: