RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM
Summative Evaluation – Clinicians

STUDY TITLE: Computer-Assisted Delivery of Therapy for Panic Disorder

STUDY INVESTIGATOR: Melanie Harned, Ph.D.

SUB-INVESTIGATOR: David Barlow, Ph.D.

STUDY SITE: Behavioral Tech Research, Inc.
4746 11th Avenue NE, Suite 102
Seattle, WA 98105

TELEPHONE: 206-957-1044

SPONSOR: Behavioral Tech Research, Inc.

You are being asked to participate in a research study. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part. This consent form describes the purpose, procedures, possible benefits and risks of the study to help you make an informed decision about whether or not you want to be part of this research. This process is known as "informed consent." This form explains how your information will be used and who may see it.

Please read this consent form carefully and contact the research study staff if you have any questions or concerns.

You may keep a copy of this consent form to think about or discuss with family or friends before choosing whether or not to participate in this study. The study staff will answer any questions you may have about this form or about the study. Please do not hesitate to ask anything about this information. Please ask the study staff to explain any words or information that you do not understand. After reading this consent form you will be asked to sign it if you would like to participate. Please keep a signed copy of this consent form for your records.

PURPOSE

You are being asked to participate in this research study because you are a clinician for individuals with panic disorder with or without agoraphobia.

We are conducting a randomized, controlled study to evaluate two methods of providing psychotherapy to adults with panic disorder. In one method, clinicians will provide treatment using their usual approach to care (called 'Care as Usual'). In the second method, clinicians will provide a specific treatment (Mastery of Anxiety and Panic treatment, also known as Panic

Control Treatment) with the help of a computer-assisted therapy (CAT) program. The main purpose of this study is to collect data from clinicians and clients to evaluate the acceptability and effectiveness of these two treatment methods.

What is the Care As Usual (CAU) treatment?

The CAU treatment is a general way of describing the approach you typically use to treat panic disorder. In other words, it means providing the treatment you think will be most helpful in treating panic disorder based on your prior experience and training.

What is the Mastery of Anxiety and Panic – Computer Assisted Therapy (MAP-CAT) treatment?

MAP is a manualized, cognitive-behavioral treatment for adults with panic disorder, with or without agoraphobia. MAP is brief (8 – 12 sessions) and highly effective, with 85% of patients panic free at the end of treatment. MAP-CAT is a web-based, HIPAA-compliant program designed to help clinicians learn and deliver MAP treatment. The MAP-CAT program provides comprehensive training in MAP and then guides clinicians through delivering the treatment during actual therapy sessions.

PROCEDURES

The study you are considering participating in is intended for clinicians who have little to no exposure to MAP and who wish to use CAT with a client with panic disorder who also agrees to take part in this study.

To participate in this study, you will be asked to identify and treat one client with panic disorder whom you determine to be appropriate for this study. Additional key elements are described below that may be helpful to you in deciding which of your clients would be appropriate to participate in this study.

About 40 clinicians and their clients will participate in this study. The length of the research study is 13 – 20 weeks. You will have up to 4 weeks to identify and recruit a client on your caseload with panic disorder to participate in this study with you. Once your client enrolls in the study, you will have up to 14 weeks to complete 12 study therapy sessions. You are <u>not</u> required to terminate treatment with your client after the study is complete.

<u>Client Criteria</u>

- 18 or older and English speaking
- Currently meets criteria for panic disorder with or without agoraphobia
- Does <u>not</u> have bipolar disorder or a psychotic disorder
- Is not at imminent risk of suicide
- Does not meet criteria for alcohol and/or drug abuse or dependence

Assuming you are willing to participate, you will first be asked to complete a pre-treatment survey online that will take approximately 30 – 45 minutes. Once you have completed this initial survey, you will then be randomly assigned by chance to one of two conditions: the MAP-CAT condition or the Care As Usual (CAU) control condition. In this regard, you have a 50-50 chance (same as a flip of a coin) of being assigned to either condition.

If you are assigned to the Mastery of Anxiety and Panic Computer-Assisted Therapy (MAP-CAT) condition, you will begin by watching a brief MAP-CAT orientation video. This video will orient you to the MAP-CAT program, demonstrate how to access training materials included in the program, and highlight key features. After watching the orientation video, you will receive access to MAP-CAT program and be given one week to review the training materials and familiarize yourself with the program. The training materials (multimedia eBooks and video tutorials) include information and resources about MAP and the use of CAT. After reviewing the training resources, you will be asked to complete a brief survey online to assess your familiarity with MAP-CAT and your initial impressions of the program. You will then be asked to approach your clients with panic disorder whom you believe would be appropriate for this study and meet the study client criteria. To preserve your client's anonymity, we have received a waiver of documentation of consent from our Institutional Review Board (IRB). This means that if your client decides to participate in this study, he/she will provide consent to the study procedures using his/her electronic signature. Potential client participants will access, read, and agree to the study via an online consent form. Potential client participants will also have the opportunity to print out the consent form and will be directed to call the BTECH-R research staff or you if they have any questions. We will provide you with the link to provide to your client so that he/she can access this consent form online, as well as additional informational materials to provide potential client participants. These materials will also assist you in answering any questions your client might have about participating in this study and will also provide tips and suggested procedures for approaching clients in an open and non-coercive manner. You will have up to 4 weeks to recruit and enroll an eligible client. During this recruitment period, you will be asked to complete a very brief (5 – 10 minutes) online survey each week. This weekly survey will ask about how many clients you have approached to participate in this study and reasons the clients agreed (or not) to participate. You will complete these brief weekly surveys for up to 4 weeks or until you enroll a client to participate in this study. If you are unable to find a client within 4 weeks, your participation in this study will be complete.

After reading and reviewing the consent form, if your client agrees to participate in this study, he/she will be enrolled in this study. He/She will then be directed to complete a pre-treatment survey online. At this point, you will be asked to complete a brief (5 minutes) survey about your therapeutic alliance with the client.

After completing this initial survey you and your client will have up to 14 weeks to use MAP-CAT in 12 weekly therapy sessions. The manner in which you use the program and how much you integrate it into your therapy sessions with this client is up to you.

After your client completes his/her pre-treatment survey, you will add him/her as your client in the MAP-CAT program. This will provide him/her with a client login/password and access to a shared dashboard of materials aimed to further facilitate his/her engagement in MAP. Your

client will be asked to use the MAP-CAT program as much or as little as he/she (and you) choose. The shared dashboard can be used throughout the study to complete homework assignments and track progress through therapy.

If you wish to continue your use of MAP-CAT with your client following your completion of the study, you may do so for up to 6 months at no charge. After 6 months, you will be able to continue your use of MAP-CAT at a discount.

If you are assigned to the Care As Usual (CAU; control) condition, you will be asked to approach your clients with panic disorder whom you believe would be appropriate for this study and meet the study client criteria. To preserve your client's anonymity, we have received a waiver of documentation of consent from our Institutional Review Board (IRB). This means that if your client decides to participate in this study, he/she will provide consent to the study procedures using his/her electronic signature. Potential client participants will access, read, and agree to the study via an online consent form. Potential client participants will also have the opportunity to print out the consent form and will be directed to call the BTECH-R research staff or you if they have any questions. We will provide you with the link to provide to your client so that he/she can access this consent form online, as well as additional informational materials to provide potential client participants and will assist you in answering any questions your client might have about participating in this study. These materials will also provide tips and suggested procedures to approaching clients in an open and non-coercive manner. You will have up to 4 weeks to recruit and enroll an eligible client. During this recruitment period, you will be asked to complete a very brief online survey each week. This weekly survey will ask about how many clients you have approached to participate in this study and reasons the clients agreed (or not) to participate. You will complete these brief weekly surveys for up to 4 weeks or until you enroll a client to participate in this study. If you are unable to find a client within four weeks, your participation in this study will be complete.

After reading and reviewing the consent form, if your client agrees to participate in this study, he/she will be enrolled in this study. He/She will then be directed to complete a pre-treatment survey online. At this point, you will be asked to complete a brief (5 minutes) survey about your therapeutic alliance with the client. After completing these initial surveys, you will be asked to treat your client's panic disorder using your usual approach. You and your client will have up to 14 weeks to complete 12 weekly therapy sessions. Upon completion of the study, you may choose to use MAP-CAT at no cost to you or your client for a period of nine months. After that, you may continue your use at a discount.

In both conditions, you can make available to your client psychotropic medications as appropriate. In other words, the research will neither restrict nor require the use of anti-anxiety or other medications for the treatment of your client's panic disorder.

Study surveys will take place online at pre-treatment (at the start of the study), mid-treatment (at six weeks), and post-treatment (after 12 therapy sessions or 14 weeks). If you are assigned to the MAP-CAT condition, you will also be asked to complete a brief online survey about your impressions of the MAP-CAT program and your use of the training resources. Access to the study surveys will be sent to you via email the week you are expected to complete the surveys

(pre-treatment, mid-treatment, and post-treatment). You will be asked to login and complete the surveys at a time that is convenient for you by the end of the week. Study surveys will ask about your demographics, psychotherapy orientation, and confidence in using certain treatment techniques. You will also be asked about your comfort using computer-assisted therapy (if assigned to the MAP-CAT condition) and applying evidence-based therapies and your therapeutic alliance. These three sets of surveys will take approximately 30 – 45 minutes to complete at each time point. In addition, both conditions will take a brief (5-minute) therapeutic alliance survey online at client enrollment.

Clients will also be asked to complete online surveys prior to your first study therapy session (pre-treatment), during the sixth week of the study (mid-treatment), and following the final therapy session (post-treatment). All client surveys will be completely anonymous and clients will not be asked to provide any identifying information. In order to further protect your client's confidentiality, he/she will not have any contact with research staff. Instead, you will be asked to help facilitate your client through the study surveys by providing him/her with instructions and an Internet link to the online surveys. Similar to the timeframe for your study surveys, client surveys will be available for completion at the beginning of the week, and your client can complete the surveys online at a time that is convenient to him/her by the end of the week. Clients will be asked about their panic symptoms and other problems they might be experiencing, their treatment experiences, their confidence that therapy is helping, and beliefs about computer-assisted therapy. Client study surveys will take approximately 30 – 60 minutes to complete at each time point. In the event that your client has difficulty completing his/her surveys at home, we may request your assistance by having your client complete the surveys at your office.

RISKS, STRESS, OR DISCOMFORT

Participation in this study is not designed or expected to create any stress or discomfort. However, participation may cause a degree of stress or discomfort for some individuals, particularly for those using a computer-assisted therapy procedure during therapy for the first time. You will be freely able to refuse participation in any part of the study and also choose to not answer a specific question or questions while completing the online surveys. You may also discontinue your participation in this study at any time.

Another possibility is that your supervisor may put pressure on you to participate in this study, thereby reducing your ability to make a genuine free choice about whether or not to participate. You are under no obligation to participate in the study at all. To ensure that participation is indeed completely voluntary and without pressure to participate by agency/program directors or supervisors, we have taken several precautions. First, we have informed them on multiple occasions that participation in this study must be completely voluntary. Second, we will not disclose to your agency/program the names of those who participated unless you specifically request (in writing) that we do so.

For your clients that you approach to participate in this study, it is possible that he/she may feel pressure from you to participate, thereby reducing his/her ability to make a genuine free choice about whether or not to participate. Participation in this study by your client must be completely

voluntary. To help lessen the possibility of this risk, we will provide you with materials to help facilitate your approach of clients to participate in this study.

Finally, there is a possibility that you or your client's confidentiality will be breached. We will implement a number of strategies to guard against a breach of confidentiality. Specifically, information collected from you will be coded with an identification number that is used to identify you. Your client will be provided with the same study identification number that will only be associated with you. The research staff will not ask for identifying information about your client. We will keep the link between your name and your identification number and all study data on a secure, password-protected computer. All servers used to transmit and store data (within the CAT program) are secure and encrypted to HIPAA compliance.

NEW FINDINGS

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

BENEFITS

There is no assurance you will receive any benefits from being in this study. Your participation may help in developing the MAP-CAT program to disseminate an empirically supported treatment for panic disorder.

ALTERNATIVES

Your alternative is not to participate in this study.

COSTS

There are no financial costs to participate in this study.

COMPENSATION FOR PARTICIPATION

Compensation for participation, described below, does not affect your standard therapy fee and arrangements for provision of treatment to your client. Reimbursement for therapy is not part of the compensation for participation.

You have two options for compensation for the treatment portion of this study. Please indicate on the signature page of this consent form which compensation option you would like to receive.

- **OPTION 1: Monetary**. The total amount of money that you receive as part of this study will be awarded to you at the conclusion of your study participation via a check mailed to the address we have on file for you. Clinicians in both conditions will receive $50.00 for completion of the mid-treatment (6-week) survey and an additional $100.00 for completion of the post-treatment (12-week) survey, for a total of $150.00. You will receive these

payments 2 – 4 weeks (by mailed check) after completion of the post-treatment survey or the end of your participation in this study.

- **OPTION 2: BTECH Bucks.** Rather than opting for cash, you can instead elect to receive BTECH Bucks for your participation in this study. BTECH Bucks are redeemable for up to one year from the date they are issued and can be used to purchase any of the online training courses offered at BTECH (go to: www.behavioraltech.org/ol/). If you opt for BTECH Bucks, you will earn an additional 15% for each dollar. For example, if you earned $150.00 of cash, you could receive $172.00 in BTECH Bucks, if opting for this option.

iPad Raffle: You will receive one raffle ticket for completion of each of the primary study surveys: pre-treatment, therapeutic alliance survey, mid-treatment, and post-treatment. You can earn up to 4 raffle tickets if you complete each survey. At the end of the study, the raffle tickets will be entered into a drawing to win one of four iPads. Each iPad will come with a $100.00 gift card to the Apple App Store.

Client Compensation: The total amount of money earned by the client will be loaded onto a prepaid Visa card at the conclusion of your study participation and mailed to you to provide to your client. Clients will have the opportunity to earn up to $225.00 for participation in this study: $75.00 for completing the pre-treatment survey, $50.00 for the mid-treatment survey, and $100.00 for the post-treatment survey.

Post-Study Use of MAP-CAT: Clinicians in both conditions will have the option to use CAT for nine months at no charge. For clinicians assigned to the CAU condition, the nine-month period of use will start upon completion of the research study. For clinicians assigned to the MAP-CAT condition, the nine-month period of use will start when they first receive access to MAP-CAT after randomization. Clinicians in both conditions will receive 9 months of use of the MAP-CAT program regardless of whether they recruit a client to participate in the study with them. In addition, we will offer access to the MAP-CAT system at a reduced fee to all clinician participants that are interested in using the system after their study access expires.

If you and/or your client do not complete the study, compensation will be issued only for the portions you do complete as described above.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You and/or your client may decide not to participate in any part of the study or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

You and/or your client's participation in this study may be stopped at any time by the investigator or the sponsor without your consent for any of the following reasons:

- If it is in your best interest
- You do not later consent to any future changes that may be made in the study plan
- One member of the study stops his/her participation in the study
- For any other reason

Your decision to participate in this study and/or to terminate your involvement in the study will in no way impact your involvement with your client in treatment and/or your decision and ability to terminate treatment with your client.

If at any point during the study period we are unable to contact you and/or your client or do not hear from you and/or your client after at least two attempts at correspondence, we will consider your participation no longer active. In this case, you and/or your client will still be compensated for the portions of the study that were completed.

CONFIDENTIALITY

As a part of this research, records that contain information or data about you and/or your client will be collected and used. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available.

The information that will be collected about you as a part of this research includes, but is not limited to, the following: your name, your address, your telephone number, your race and gender, and results from study procedures. Information that will be collected about your client includes, but is not limited to the following: his/her race and gender, current psychological functioning, and results from study procedures. The server used to collect and store treatment data from MAP-CAT are HIPAA compliant and all research staff has completed HIPAA training.

Information from you will be coded with a study identification number. We will keep the link between your name and identification number in a separate, secured location for no longer than six months following the date of your final study assessment. Then we will destroy the link. Your client will be identified to study staff using only your study identification number. Study staff will not ask for your client's name or other contact information.

Because we are conducting this study in collaboration with David Barlow, Ph.D., from the Center for Anxiety and Related Disorders at Boston University, data from this study will be shared with Dr. Barlow. To ensure that confidentiality will be fully maintained, documents will only include your identification number, if an identifier is provided at all.

The following groups may review and use your study information. They may review your study information to make sure that it is correct. They may also review your information to make sure that the study is being conducted properly.

- *The study sponsor* (or sponsor representatives such as monitors and/or auditors)

and may be looked at and/or copied for research or regulatory purposes by:

- *Sterling Institutional Review Board (IRB)*
- *The Department of Health and Human Service (DHHS)*

Absolute confidentiality cannot be assured because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

This permission (also called an authorization) will last until the link between your name and study number is destroyed.

You may also take away (or withdraw) your permission for the use of your information at any time. If you choose to withdraw your permission, you must do so in writing. If you withdraw your permission after you have entered the study, you cannot continue participating in the study. The investigator will still be able to use the information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

SOURCE OF FUNDING

Funding for this research study will be provided by the National Institute of Mental Health.

QUESTIONS

If you have any questions, concerns or complaints about the research or your participation in this study or if at any time you feel you have experienced a research-related problem contact:

Study PI: Dr. Melanie Harned	Study Coordinators: Angela Kelley and Sean Tully
Phone: 206-675-8588	Phone: 206-957-1044
Email: mharned@btechresearch.com	Email: info@btechresearch.com

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free). You may contact Sterling Institutional Review Board IRB if the research study staff cannot be reached or if you wish to talk to someone other than the research team. Sterling IRB will not be able to answer some study-specific questions, such as questions about appointment times.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

CONSENT

I have read the information in this consent form. This study has been explained to me. I have had a chance to ask questions. All of my questions about the study and my participation in it have been answered. I volunteer to take part in this research. I will get a signed copy of this consent form, which has 10 pages, for my records.

I authorize the release of my research records for research or regulatory purposes to the sponsor, DHHS agencies, and Sterling IRB.

By signing this consent form, I have not given up any of my legal rights.

Please indicate which payment method you would like to receive for your participation in this study:

_____ I am interested in receiving payment **in the form of a check** for my participation in this study.

_____ I am interested in receiving payment **in the form of BTECH Bucks** for my participation in this study.

I verify that I will only offer this opportunity to clients(s) who:

- Currently meet diagnostic criteria for panic disorder with or without agoraphobia.
- Are currently older than the age of 18 years
- Are not at imminent risk of suicide
- Do not meet criteria for current mania, psychotic disorder, or alcohol and/or drug abuse or dependence.

By signing my name in the space below, I verify I will only discuss this opportunity with those clients who, to the best of my knowledge, meet the study conditions.

Signature of Research Participant	Printed name	Date

Signature of Person Conducting Informed Consent Discussion	Printed Name	Date