PARTICIPANT INFORMED CONSENT FORM
Summative Evaluation – Clients

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 the following 7 pages carefully and contact the research study staff or your therapist 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. Your therapist will answer any questions you may have about this form or about the study. Please ask your therapist to explain any words or information that you do not understand. You can also call the Behavioral Tech Research offices to discuss this study with our research staff. Please do not hesitate to ask any questions about the information provided in this form. Please ask your therapist to explain any words or information that you do not understand. After reading this consent form you will be asked to provide your electronic signature indicating that you would like to participate in the study. Do not provide your electronic signature if you do not want to participate. Please keep a copy of this consent form for your records.

PURPOSE

You are being asked to participate in this research study because you currently are in, or are about to begin, treatment for panic disorder with or without agoraphobia (a fear of being in places where escape might be difficult or where help might not be available).

The main purpose of this study is to evaluate two methods of providing treatment to adults with panic disorder. In one method, therapists will provide treatment using their usual approach to care. In the second method, therapists will provide a specific treatment (called Mastery of Anxiety and Panic treatment) with the help of a computer-assisted therapy program.

If you choose to participate in this study, you will receive the treatment method randomly assigned to your therapist. Your therapist will have had a 50-50% chance of being assigned to use their usual approach to care (Care As Usual or simply CAU) or to use the Mastery of Anxiety and Panic – Computer Assisted Therapy (MAP-CAT) program. This will have been decided randomly (like the flip of a coin) by the research staff before you begin participation in the study.

PROCEDURES

To participate in this study, you will be asked to engage in therapy for panic disorder with your therapist who is also participating in this study. You and your therapist will not be asked to provide any identifying information about you for the purposes of the study (e.g., your name or contact information), and you will not be asked to contact the research staff during your participation in this study. This means that your identity will remain anonymous while you participate in the study.

About 40 men and women with panic disorder and their therapists will participate in this study. The length of the study procedures you will be asked to take part in will be 12 – 15 weeks. Once you enroll in this study, you and your therapist will have up to 14 weeks to complete 12 study therapy sessions. You may decide to continue treatment with your therapist after the study is complete.

If your therapist is assigned to the MAP-CAT condition, you and your therapist will have up to 14 weeks to use the MAP-CAT program during 12 weekly therapy sessions. You may be asked to log in to the program outside of therapy sessions in order to complete homework assignments. It will be up to you and your therapist to decide if you will use the program outside of therapy sessions. If you and your therapist wish to continue use of MAP-CAT following completion of the study, you may do so for 6 additional months.

If your therapist is assigned to the Care As Usual (CAU) condition, your therapist will be asked to treat your panic disorder using their usual approach to treatment for panic disorder. In other words, your therapist will provide the treatment they think will be most helpful to you in treating your panic disorder. You and your therapist will have up to 14 weeks to complete 12 weekly therapy sessions. Upon completion of the study, you and your therapist may choose to use the MAP-CAT program at no cost to you or your therapist for up to nine months.

In both conditions, you may use medications to help with your panic disorder if you and your therapist decide so. In other words, the research will neither restrict nor require the use of anti-anxiety or other medications for the treatment of your panic disorder.

There are a total of three study surveys involved in this research study. These online surveys will take between 30 – 60 minutes to complete and can be completed at a time that is convenient to you. Your therapist will ask you to complete these online surveys prior to your first study therapy session (pre-

treatment), during the sixth week of the study (mid-treatment), and following your final study therapy session (post-treatment). All client surveys will be anonymous and clients taking part in this study will not be asked to provide any identifying information. In order to further protect your confidentiality, you will not have any contact with research staff as you complete these surveys. Your therapist will provide you with the information you need to complete the study surveys. The surveys will ask about your panic symptoms and other problems you might be experiencing, your treatment experiences, your confidence that therapy is helping, and beliefs about computer-assisted therapy. In the event that you are having difficulty completing your surveys at home, your therapist may offer to provide assistance by, for example, having you complete the surveys at his/her office. All information you provide in the surveys will be kept confidential. This means that your therapist will not have access to your survey responses.

POTENTIAL RISKS, STRESS, OR DISCOMFORTS OF THE STUDY

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 and early on during therapy. To lessen any discomfort caused by the study, the procedures were designed to allow you to complete the study surveys in the comfort of your own home. Additionally, you will always be freely able to refuse participation in any part of the study or not answer a specific question or questions during the research surveys without compromising your treatment. You may also discontinue your participation in this study at any time, without in any way impacting your treatment.

Another possibility is that you may feel pressure from your therapist to participate in this study, thereby reducing your ability to make a genuine free choice about whether or not to participate. To ensure that participation is indeed completely voluntary, your therapist has been informed on multiple occasions that your participation in this study must be completely voluntary.

Finally, there is a possibility that your confidentiality will be breached. **You are under no obligation to participate in the study at all.** The Sponsor has a number of strategies to guard against a breach of confidentiality. Specifically, information collected from you and your therapist will be coded with an identification number that is used to identify only your therapist. This identification number will allow us to link your responses to your therapist, while keeping your identity anonymous. The link between your therapist's name and his/her identification number and all study data will be kept in a secured, locked file cabinet and/or on a secure, password-protected computer. All servers to transmit and store data (within the MAP-CAT program) are secure and encrypted to HIPAA compliance.

NEW FINDINGS

Your therapist will tell you about any new information that might change your decision to be in this study. You may be given a revised consent form and asked to consent to continue the study if this occurs.

BENEFITS

There is no assurance that you will receive any benefits from being in this study. Your panic disorder

may stay the same or get worse. Your participation may help in developing MAP-CAT for the treatment of panic disorder, which may help clients in the future.

ALTERNATIVES

Your alternative is not to participate in this study. You may receive therapy for your condition without participating in the study.

COSTS

There are no financial costs to participate in this study.

COMPENSATION FOR PARTICIPATION

Compensation for participation, described below, does not affect your therapist's standard therapy fee and arrangements for treatment. Reimbursement for therapy is not part of the compensation for participation.

You will have the opportunity to earn up to $225 for participation in this study: $75 for completing the pre-treatment survey, $50 for the mid-treatment survey, and $100 for the post-treatment survey. The total amount of compensation that you will receive as part of this study will be loaded on a prepaid Visa card at the conclusion of your study participation. The prepaid Visa card will be mailed to your therapist and s/he will be asked to give it to you. This will enable you to receive compensation for participating in the study without having to provide us with your name or contact information.

If you do not complete the study, you will be compensated only for the portions you do complete as described above.

Post-Study Use of MAP-CAT: Therapists and clients assigned to the CAU condition will have the option to use MAP-CAT for up to 9 months at no charge upon completion of the research study. Therapists and clients in the MAP-CAT condition may continue to use MAP-CAT for up to an additional 6 months at no charge upon completion of the research study.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You 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.

Your 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
- Your therapist stops their participation in this study

- For any other reason

Your participation may also be stopped by your therapist at any time if it is interfering with your therapy or 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 in treatment and/or your decision and ability to terminate treatment.

CONFIDENTIALITY

As a part of this research, records that contain information or data about you will be collected and used. Study data that is collected from you will be anonymous. If any records identifying you are collected, they will be de-identified immediately.

The information that will be collected about you as a part of this research includes, but is not limited to, the following: your race and gender and results from study procedures.

Information from you will be coded with a study identification number that is linked to your therapist. The research staff will keep the link between your therapist's name and identification number in a separate, secured location for no longer than six months following the date of your final study assessment. The link will then be destroyed.

Because the study is being done 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, any data that is shared will only include your therapist's 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 therapist's identity will not be disclosed in those presentations.

This permission (also called an authorization) will last until the link between your therapist's 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 (IRB) 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 IRB if the research team 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 agree to participate in this study unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

CONSENT & AUTHORIZATION

To participate in this research, indicate that you are willing and interested in taking part in this study.

By participating in this study, you verify that you have read the information in this Participant Informed Consent Form and that all your questions have been answered. If you have not had a chance to ask questions, please do so with your therapist now or call the research study offices at 206-957-1044. If you have questions later about the research, you can ask your therapist or anonymously call the study staff listed above or another member of the research team. You may keep this copy of the consent form for your records.

By checking the box below, you are agreeing to the information contained in this consent form, you have not waived any of the legal rights which you otherwise would have as a research participant in a research study.

Would you like to participate in this study?

- ○ No, I am not interested in participating in this study. By choosing this option I am choosing not to enroll in this study.
- ○ I would like to think more about this study before choosing to participate or not.
- ○ Yes, I would like to participate in this study. By choosing this option, I am providing my electronic signature and enrolling in this study. Please also provide your therapist's name:

  _____ (therapist)

Please use one of the following options to return this form to the research study staff:

- Confirm your choice electronically *via the emailed link from your clinician*
- Return a copy of this completed form to your therapist who will send it to our study staff
- Fax a copy of this completed form to the research study staff at 1-206-957-0518
- Mail a copy of this completed form to the research study staff to the following address:
  Behavioral Tech Research
  4746 11th Ave. NE, Suite 102
  Seattle, WA 98105

If you choose to fax or mail this form to our offices, please remember not to include your name or contact information on the document, fax cover sheet, or envelope. If you would like to include a return address on your envelope, you can use your therapist's address or the address of the research study office (above).