

## Informed Consent

### *The Mindfulness and Acceptance Workbook for Anxiety: Evaluating the Effectiveness of a Self-Help Intervention in the Alleviation of Anxious Suffering*

#### **Investigators:**

This research is being conducted by Sean C. Sheppard, B.A., Doctoral Student and Project Coordinator, and John P. Forsyth, Ph.D., Associate Professor of Psychology and Director of the Anxiety Disorders Research Program, of the University at Albany, State University of New York.

#### **Purpose:**

Drs. John P. Forsyth and Georg H. Eifert just published a new self-help workbook for people suffering with any anxiety problem. The book is called *The Mindfulness and Acceptance Workbook for Anxiety: A Guide to Breaking Free From Anxiety, Phobias, and Worry Using Acceptance and Commitment Therapy*. The purpose of this research is to find out if *The Mindfulness and Acceptance Workbook for Anxiety* is helpful in alleviating anxious suffering and improving quality of life, and in what ways the workbook might be helpful.

#### **What is Involved?:**

This project has several parts. Here, we describe them in some detail.

1. **Initial Screening and Assessment Procedure.** If you decide that you would like to participate in this study, you must check the appropriate box below. This tells us that you have read this Informed Consent and are willing to participate. Once you click that box, you will be asked to complete the Initial Demographic/Eligibility Survey. This survey asks some basic background information about yourself to help us decide if your participation in the study is appropriate. Based on your responses, the researchers will make a decision about your eligibility for participation. If you are ineligible, we will notify you via email. If you are eligible, we will email you with a link to complete the Initial Questionnaire Assessment which will consist of a series of questions about your experience with anxiety, fears, and the like, including how you cope with anxiety, and overall about your quality of life. This portion of the study will take you approximately 40 minutes. So, please do not go on unless you have the time to complete the full questionnaires. The Survey Monkey will not allow you to save your work and login at a later time to finish.
2. **The Workbook Phase.** Once you complete the initial questionnaires, you will be randomly assigned to receive the workbook right away or to wait for about 12 weeks before receiving the workbook.
  - a. If you are assigned to receive the workbook right away, we will mail you a copy of the workbook and the accompanying audio CD, along with a brief letter describing the study and how to use the workbook. You will be asked to work with the workbook at your own pace over a 12 week period and to complete 10 brief (5 minute) online self-assessments following some of the chapters (we will mark these spots with brightly colored paper that have instructions about how to complete the chapter self-assessments online). The workbook provides information and many exercises that we think will be of help to you, and the CD contains extra copies of printable forms and worksheets plus several audio mindfulness and acceptance exercises to help you develop important new skills. At the end of the 12 week period, we will email you a link to SurveyMonkey asking you to repeat the Initial Questionnaire Assessment. After that, we will ask you to repeat that assessment survey again two more times: at week 24 and at week 36. These later assessments are really important so that we can figure out if people like you continue to benefit and maintain their progress in the long-term (where it really counts). We will send you email reminders with links to SurveyMonkey so that you can do the three larger questionnaire assessments – once 12 weeks from now, and then 3 months and 6 months after that. Each of the three assessments will be identical to the first one and ought to take no more than 40 minutes of your time. To clarify, over the course of the study you will be asked to complete (a) your formal reading and practice with the workbook at your own pace within 12 weeks, (b) four larger

- questionnaire assessments, and (c) 10 short chapter self-assessments online at Survey Monkey, a secure online service.
- b. If you are assigned to wait for 12 weeks before receiving the workbook, please do not lose hope. Your role in this project is important, for without you we would not be able to tell if the workbook is helpful relative to doing nothing at all. If you are in the waiting group, you will only have to wait for 12 weeks. After that, we will send you your free copy of the workbook and ask you to work with it at your own pace just as we will do for those people who get the workbook right away. You will be asked to do everything that we ask of the people that get the workbook right away (see 2a above). We are interested in knowing whether and how the workbook is helpful to everyone in this study, it's just that some people get started sooner than others. We hope you understand and are willing to delay getting the workbook if you happen to be randomly assigned to this condition.
3. **Optional ACTforAnxiety Message Forum.** The ACTforAnxiety.com study website has a link to a free online message forum we have set up for people enrolled in this study. You can find it at <http://www.ACTforanxiety.proboards54.com>. This message board is limited to study participants and provides a place for you and others enrolled in this study to post comments, share ideas, and to provide support for one another as you all work with the workbook. Participation in the message forum is entirely optional. If you choose to participate in the ACTforAnxiety message forum, information collected online at registration is limited to personal email addresses and birthdays. Email addresses will be used by Proboards.com to provide a "key" for you to begin to use the message forum service. Birthdays are collected in compliance with US law. When asked to provide your personalized screen name, you should use your assigned study identification number (found inside your workbook). You should also opt to hide your email and age from other participants upon registration for the message forum. Your message board membership approval will be contingent on these selections. Complete instructions for this service are available at the study website: [www.ACTforAnxiety.com/ACTforAnxiety\\_Study\\_Index.html](http://www.ACTforAnxiety.com/ACTforAnxiety_Study_Index.html).

### **What are the Risks?:**

There are no known risks associated with participation in this study. You may experience some mild discomfort as you think about and answer some of the questions on the questionnaires. The questions may also help you gain clarity and insight about your life and experience with anxiety too. Mild discomfort, along with the full range of other human emotional experiences, might occur as you read and engage in *The Mindfulness and Acceptance Workbook for Anxiety*. Some of the exercises encourage you to come into more honest and direct contact with uncomfortable thoughts, feelings, and memories so that you can practice learning a new way of relating with them, and thus live better with them. Other exercises focus on teaching you how to be more compassionate and kinder with yourself and others. Much of this work may feel backwards at times, and people who engage the exercises in this book report a range of thoughts and experiences along the way, some pleasant, some familiar and unpleasant, and others just neutral. Please know that you are free to end your participation at any time, and you will be able to consult a list of mental health crisis and referral services on the study website at any time or by contacting the investigators.

### **What are the Benefits?:**

We cannot promise you will benefit by participating in this study. The tools and strategies contained in the workbook have been shown to help people suffering from many types of problems, and we hope to find out if the workbook can do the same for you and people just like you. Everyone is unique. The strategies in the workbook are probably quite different from most strategies that you have used before. This is good in the sense that by doing something new, you risk getting a different outcome in your life. We don't know exactly what that might be for you, but our main goal is to learn something about how this workbook helps people like you, and hopefully something about how it is helpful. This is the first study of its kind to find out if *The Mindfulness and Acceptance Workbook for Anxiety* is helpful and in what ways it is helpful.

### **Costs/Compensation:**

There is no cost for participating in this study. You will receive a free copy of *The Mindfulness and Acceptance Workbook for Anxiety*. Because we do not have a grant or other means to support this study, we are limited in what we can do to compensate you for completing the online questionnaire assessments. Yet, we will set up a lottery system for those that complete the larger assessment questionnaires 12 weeks from now, and again at the 3 and 6 month follow-up period. These larger assessments are really important for this study, for without them we will not be able to know whether the book helped you and people like you and in what ways it helped. For the lotteries, all you need to do is complete the larger questionnaire assessments when prompted to do so when we email you. Once you do them, we will enter your study number in a random lottery to win a \$25 gift certificate from [www.amazon.com](http://www.amazon.com). You will have a 1 in 50 chance to win a gift certificate each time you complete the larger questionnaire assessments, and you can win a gift certificate more than once. So, if you complete the questionnaire assessment 12 weeks from now, and again at 3 and 6 month follow-up, you may win up to \$75 in Amazon gift certificates.

### **Confidentiality:**

We will make every effort within the law to protect the confidentiality of your records and personal information. All information obtained in this study is strictly confidential unless disclosure is required by law. In addition, the Institutional Review Board and University or Government officials responsible for monitoring this study may inspect these records. You will not be personally identified in any reports or publications from this study.

At the beginning of the study, you will be assigned a study number known only to you and the investigators. Your name and personal information you will provide on the Initial Questionnaire Assessment will be purged from that file and kept securely under lock and key in Dr. Forsyth's laboratory. We will also keep it separated from all other study material and will destroy paperwork with your identifying information at the end of the study, or approximately nine months from now. All the online questionnaires and chapter self-assessment quizzes are anonymous and will never require you to input your name or other personal information.

Questionnaires and quizzes are facilitated through Survey Monkey, an online secure service. Completion of the questionnaire sets and quizzes will be possible through links sent by us to your email. These links and all information collected on Survey Monkey will be secured by SSL encryption. SSL encryption is the same system used by banking and other commercial institutions and is considered to be the highest level or "gold standard" of online data protection. The account with Survey Monkey is protected with a screen name and password known only to the investigators.

In order to maintain as much confidentiality as possible, we suggest (but do not require) that you create a special email account specifically for the purposes of this study. To create a free yahoo email account, visit [www.yahoo.com](http://www.yahoo.com), click on "Free Mail: Sign Up" found near the top center of the page, and follow the prompts. You can also set up a free email account via Google, or another service of your choosing.

This project has been approved by the University at Albany Institutional Review Board. Approval of this project only signifies that the procedures adequately protect the rights and welfare of the participants. Please note that absolute confidentiality cannot be guaranteed due to the limited protections of Internet access. Please be sure to close your browser when finished so that no one will be able to view your responses.

### **Participation Is Optional:**

Your participation in this project is voluntary. Even after you agree to participate in the research or sign the informed consent document, you may decide to leave the study at any time without penalty or loss of any benefits to which you may have otherwise been entitled. You may also choose not to answer any of the questions although we hope you will attempt them all.

### **Contact Information:**

If you have any questions related to this study, please contact:

1. Study email: [ACTforanxiety@gmail.com](mailto:ACTforanxiety@gmail.com)

2. Sean C. Sheppard, Doctoral Student & Project Coordinator, University at Albany at 518-591-8505.
3. Dr. John P. Forsyth, Associate Professor of Psychology, University at Albany at 518-442-4862.

**IRB Contact Information and Human Rights Statement:**

If you have any questions concerning your rights as a research participant that have not been answered by the investigators, or if you wish to report any concerns about the study, you may contact the University at Albany Office of Research Compliance toll free at 1-800-365-9139 or [orc@uamail.albany.edu](mailto:orc@uamail.albany.edu).

Please print a copy of this document, so that you have on hand the contact information for the investigators and the Office of Research Compliance.

By checking this box, I acknowledge that I have read, or been informed of the information about this study. I hereby consent to participate in the study. (Box is provided on study website site [see Sign Up page] and will not let you advance in the study unless they have checked it.)