



## INFORMED CONSENT FORM

Protocol Title: Testing the efficacy of <i>Opening Doors</i> : A career guidance intervention for individuals with psychiatric disabilities.
Principal Investigator: Uma Chandrika Millner, Ph.D.
Description of Subject Population: Individuals diagnosed with psychiatric conditions
Version Date: October 23, 2015

### Introduction

Please read this form carefully. The purpose of this form is to provide you important information about taking part in a research study. If any of the statements or words in this form is unclear, please let us know. We would be happy to answer any questions.

If you have any questions about the research or any portion of this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study we will ask you to sign this form. We will give you a copy of the signed form.

The person in charge of this study is Uma Chandrika Millner, Ph.D. Dr. Millner can be reached at the Center for Psychiatric Rehabilitation at 617-353-3549 or [umillner@bu.edu](mailto:umillner@bu.edu). We will refer to this person as the “researcher” throughout this form.

### Why is this research study being done?

The purpose of this study is to test whether a new career guidance intervention called *Opening Doors* can improve the employment outcomes for individuals diagnosed with psychiatric conditions. This is a research project. This study is being conducted by the Center for Psychiatric Rehabilitation of Boston University. If *Opening Doors* is effective, it may help other people dealing with psychiatric conditions seek jobs that are in line with their values, interests and goals.

About 144 individuals with psychiatric conditions will participate in this study.

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**Boston University** College of Health  
& Rehabilitation Sciences: Sargent College  
Center for Psychiatric Rehabilitation

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The funding for this research project is provided by the National Institutes for Disability Rehabilitation and Research.

The findings from this study may be presented at professional conferences and in journal articles.

### **How long will I take part in this research study?**

We expect that you will be in this research study for one year. During this time, we will ask you to make approximately 28 study visits to the Center for Psychiatric Rehabilitation at Boston University.

### **What will happen if I participate in this study?**

If you agree to be in this study, you will have the opportunity to participate in a new intervention called *Opening Doors* designed to help individuals with psychiatric conditions develop plans to achieve their career goals. Since this is an experimental research study, you have a 50/50 chance of receiving this new intervention. Decisions about whether to offer you the new intervention will be made in a random manner.

If you are offered the new intervention and you agree to participate, you will be invited to attend the *Opening Doors* program that includes group meetings and individual sessions with a trained career counselor over the course of about 12 weeks. The group portion of *Opening Doors* will consist of 90 minute sessions twice a week for the first 8 weeks and once a week for the remaining 4 weeks. The group meetings will include other individuals with psychiatric conditions. We will ask you to meet with your individual career counselor for at least 1 individual session at the beginning of the program and from around the eighth week, you will have the opportunity to meet individually with the counselor every week for 45 minutes. In these 1:1 sessions, the counselor will help you develop and achieve your career plans. The study will run for one year which includes the 12 weeks of the *Opening Doors* intervention.

If you are not offered the *Opening Doors* intervention, you will be placed on a waiting list and you can enroll in *Opening Doors* after the study has been concluded in 12 months. In the meantime, you can sign up for life skills classes at the Recovery Center. However, these classes cannot include any vocational training or services. There are no restrictions on your participation in vocational services or programs outside the Center, regardless of which group you are in.

When you sign up for classes at the Recovery Center (including *Opening Doors*), you will be

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asked to register as a student at the Recovery Center.

We will ask you to complete questionnaires whether you receive the *Opening Doors* intervention or not. You will have the choice of completing these questionnaires using hard copies or via the internet with help from a research staff. These questionnaires will include demographic questions such as, your age, gender, mental health status, diagnoses, employment history and activities. We will also collect your diagnosis from your psychiatric service provider. In order to do so, we will ask you to sign a release of information form authorizing the release of this to us. If you choose not to sign the release of information form, we will ask you to report your diagnosis to the best of your knowledge.

We will ask additional questions about your work goals and hopes, readiness for working and how you are managing on a day-to-day basis. These questionnaires will take about 60 minutes to complete. We will ask you to complete these questionnaires at the beginning of the study and four times after that every 3 months. We will also be in touch with you every month to answer some brief questions about your employment activities every month. If you are participating in *Opening Doors*, you will be asked to complete a very short questionnaire (three questions) at the end of each group and individual Opening Door session about your experience during the session.

### **Will I be paid for taking part in the study?**

You will be paid \$25 for each of the five times you complete questionnaires for this study. You may also receive three bonuses. If you complete the questionnaires three times (at 6 months), you will receive additional \$5, if you complete the questionnaires four times (at 9 months), you will receive additional \$10, and if you complete the questionnaires five times (at 12 months), you will receive an additional \$15. If you begin this informed consent (even if you do not sign the consent form) or any of the follow-up interviews, but do not finish them, you will be given a partial payment of \$10. We will reimburse any public transportation expenses you may have incurred in order to come to the Center to complete the questionnaires, as long as you can give us a receipt. If travel to the Center to attend the *Opening Doors* intervention becomes a problem for you in terms of cost, please inform us and we will work with you to help pay for those expenses.

In order for us to pay you for your participation, we will need your name and mailing address on the receipt. We will pay you by check if you complete the surveys online or if we need to mail you travel reimbursement. In order for checks to be processed, the payment has to go through

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Boston University Central Offices who has temporary access to your name and address. Your name and address will only be used for payment purposes. Hard copies of receipts with your name and address will be stored in locked cabinets.

### **How Will You Keep My Study Records Confidential?**

All information collected from the questionnaires and interview will be confidential and will be stored in a secure location at the Center for Psychiatric Rehabilitation of Boston University. Your name will not be kept with our records of the questionnaires and interviews. Your answers to the questions will be entered into electronic files, but will not contain your name or any other identifying information. You will be given an ID number that has no relationship to your name or other identifying information. Only this number will be listed on your questionnaire responses. The master list connecting this ID number as well as this form will be kept separately in a locked file cabinet at the Center for Psychiatric Rehabilitation. We will keep the master list and the informed consent form separate from your responses to the questionnaires. Only the study staff and oversight groups will see these documents.

All individual and group meetings for Opening Doors will be confidential. We will ask you and the other people in the group to you not to tell anyone outside the group what any particular person said in the group. However, we cannot guarantee that other group members will keep the discussions private.

This form will be kept separately in a locked file cabinet at the Center for Psychiatric Rehabilitation, BU. This form will be kept for seven years from the beginning of this study. Only the study staff and oversight groups will be able to see these forms. Your answers to the questionnaires will be kept until the data has finished being analyzed, which likely will be in 2025. All personal identifying information will be removed prior to electronic storage of information. Information stored electronically will be will uploaded into password-protected files with access restricted to research staff and study oversight groups.

The findings from the study will not identify any individual. Only group results will be discussed. No individual will be identified in any report or other written material.

Other parties may inspect this form for regulatory purposes; these may include the U.S. Department of Health and Human Services, the National Institute on Disability and Rehabilitation Research, Central Office Research Review Committee (Department of Mental Health), and the Boston University Institutional Review Board. However, no other party has rights to your personal information. No other party will receive your personal information or will be allowed into your files.

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Confidentiality will be protected to the extent allowed by the law. For example, if we determine from the information that you provide that you or any other person is at risk or may have been abused, we may be required to notify the appropriate authorities. We are required to report abuse or threats of harm to you or others to appropriate authorities. If this were to happen, we would attempt to discuss this with you first.

At the conclusion of the study or seven years after the study is concluded, we will destroy this form as well as the master list linking your study ID to any identifying information.

### **What are the risks of taking part in this research study?**

We see very little risk to you from taking part in the study. You may withdraw from the study at any time and may request for your study data to be destroyed.

You may experience minor psychological discomfort as a study participant when discussing psychiatric symptoms or work issues during the group or individual sessions or while completing the questionnaires. If you experience discomfort during group sessions, you may take breaks, leave the room, or stop participating in the group altogether. You may also request immediate support from study staff to deal with this discomfort. You may reschedule individual sessions if you experience any discomfort. You may also decline to discuss certain topics. If you experience any discomfort while completing the questionnaires, you can refuse to answer specific questions, reschedule the interview session, or refuse to complete the interview or participate in the remaining interviews. When responding to the questionnaires, you may take as much time as needed to respond to any of the questions.

Although we will take all the steps necessary to maintain confidentiality during the group meetings for Opening Doors, we cannot guarantee that every participant in the group will keep the discussions private. Possible loss of confidentiality is a risk of participating in this study.

All information you provide will be confidential and won't be shown to your mental health providers. No matter what your answers are, they will not affect your mental health services at all. If at any time you decide to withdraw from the study, your decision will not affect your mental health services, except that you will no longer be getting *Opening Doors* services.

If you are currently receiving disability benefits, or expect to receive them in the future, going to work can affect those benefits. There are disability benefits counselors who can inform you about the issues and risks specific to your circumstances. If you wish, we will connect you with a disability benefits counselor, either now, or in the future.

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If new information becomes available that may change the risks of being in this study, or might change your decision to be in this research project, you will be notified in a timely fashion.

### **Study Participation and Early Withdrawal**

Your participation in this study is completely voluntary. Taking part in this research study is up to you. You have the alternative of not participating in this study. If you participate, you may freely withdraw from the study at any time. Your decision not to participate or to withdraw from the study will have no effect whatsoever on any services or benefits you receive. If you are a DMH client, your access to DMH services will not be affected.

Your participation in this study may be stopped at any time by research staff, without your consent, if they feel that it is in your best interest, the interest of other members of the group, or if you do not follow study procedures.

### **What alternatives are available?**

You may choose not to take part in this research study.

### **What will it cost me to take part in this research study?**

There are no costs to you for taking part in this research study.

### **Is there any benefit to the study?**

If you participate in the *Opening Doors* intervention, you may understand more about your work values, interests, and goals. It may also become easier for you to get and keep a job.

The new *Opening Doors* intervention will be refined based on your participation and input. If the intervention is effective, it may help other people who are dealing with psychiatric conditions seek jobs that are in line with their values, interests and goals.

### **If I have any questions or concerns about this research study, who can I talk to?**

You can call us with any concerns or questions. Our telephone numbers are listed below:

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If you have questions about your rights as a research subject or want to speak with someone independent of the research team, you may contact the Boston University IRB directly at 617-358-6115.

### Statement of Consent

I have read the information in this consent form including risks and possible benefits. I have been given the chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study.

### SIGNATURE

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

\_\_\_\_\_  
Name of Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

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