Consent Form for Adult Participants at the Institute for Community Living for IRB-FY2017-1002

Project Title: Engaging Young Adults in Their Mental Health Care through a Brief Empirically-Based Meta-Intervention

Principal Investigator: Michelle Munson
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Key Information: You are being asked to participate in this research study because you are receiving services at The Institute for Community Living. This research study aims to improve mental health service use and outcomes for youth and young adults aged 18 to 30 who are transitioning to adulthood. If you agree to be in this study, you will be asked to do the following:

1. Be randomly assigned to one of two groups: Just Do You Meta-Intervention (experimental group) or Best-Available-Services group (BAS). If you are a participant in the experimental group you will be asked to attend two modules, which last 90 minutes and attend all regularly scheduled PROS sessions. If you are a participant in the best available services group you will be asked to attend regularly scheduled PROS sessions.
2. Complete four assessment interviews, lasting about 60 minutes each.

Participation in this study will involve six hours of time. There is a low likelihood of foreseeable risk involved in the study. In particular, the only minor risk is emotional discomfort answering questions, and we will provide time for breaks and remind you multiple times that the study is voluntary and you can stop at any time. There is no direct benefit, but an important indirect benefit is assisting the researchers in advancing knowledge to assist other young adults like you receive the highest quality mental health services possible.

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Please read the rest of this consent form for more information about the study.

Introduction/Purpose: You are being asked to participate in this study because you are receiving services at The Institute for Community Living. This research aims to improve mental health services for youth and young adults aged 18 to 30. This study is being conducted by Michelle Munson, a faculty member at the Silver School of Social Work, New York University. If you give consent to participate in this study, you will be randomly assigned to one of two groups: Just Do You Meta-Intervention or Best-Available-Services group (BAS).

Procedures: If you are randomly assigned to the BAS group, you will be encouraged to attend regularly scheduled PROS appointments and any other (non-Just Do You) services provided at The Institute for Community Living. These sessions last 45 minutes. If you are randomly assigned to be in the Just Do You group, you will be asked to meet for 2 meta-intervention group sessions, which each last 90 minutes and attend regularly scheduled PROS appointments and any services provided at The Institute for Community Living.

The experimental procedures in this research differ from the standard treatment. For example, Personalized Recovery Oriented Services (PROS) does not currently have a orientation program. This project is testing the efficacy of an orientation program for young adults. You should know that if you are assigned to

receive the engagement intervention, we cannot guarantee that it will be more effective than the standard engagement in the PROS program.

It is important to note that the investigator may withdraw you from the study without your consent if your symptoms worsen as identified by the PROS staff providing the engagement intervention modules.

A research assistant may be present during sessions to observe the procedures that are followed.

In addition to the above described sessions, this study will ask that you contribute the following amount of time:
• Assessment 1 (60 minutes) – Both Just Do You and BAS group
• 2-week post-test (60 minutes) – Both Just Do You and BAS group
• 4-week follow-up (60 minutes) – Both Just Do You and BAS group
• 3 month follow-up (60 minutes) – Both Just Do You and BAS group

Audio-Recording: Some sections of your interviews will be audio-taped so that we can capture your responses in their entirety. In addition, if you attend the Just Do You group, some of the group sessions will be audio-taped. You may review these tapes and request that all or any portion of the tapes that includes your participation be destroyed.

Confidentiality: Confidentiality of your research records will be strictly maintained by assigning code numbers to each participant so that data is never directly linked to individual identity. Also, we will keep all completed forms in a locked cabinet only accessible to the project staff. Your name will never be written in any of our reports. Your responses will be kept confidential with the following exception(s): the researcher is required to report to The Institute for Community Living any suspicion of harm to yourself, to children, or to others. Agency staff will follow agency protocol for each situation. Also, the researcher cannot guarantee that other youth in the 2-session group will maintain confidentiality.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results, but will never include information that can identify you. You can search this website at any time.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This coverage means that most people outside the research team or those responsible for overseeing the research will not see your name on your research information, including people who try to get your information using a court order in a federal, state, or local civil, criminal, administrative, or legislative case or action. One exception is if you agree that we can give out research information with your name on it. Other exceptions are if there is a federal, state, or local law that requires disclosure, such as information about child abuse or neglect and harm to yourself or others.

Voluntary Participation: Your participation is voluntary. You may refuse to participate at any time without penalty. You also have the right to skip or not answer questions that you prefer not to answer. Nonparticipation or withdrawal will not affect your services delivered at The Institute for Community Living clinics.

Possible Discomforts and Risks: It is possible you may experience emotional discomfort while completing the assessments. If this occurs, you are welcome to take a break, skip any questions, or end the assessment at any time. Substantial emotional discomfort caused by the measures being administered will be handled in a prompt, professional manner by clinicians and counselors at The Institute for Community Living who will provide any clinical medical attention necessary.

Benefits: There are no direct benefits to you for participating in this study. One indirect benefit may be the opportunity to share some of your experiences in order to help the researchers better understand the needs and opinions of older adolescents and young adults. Another possible benefit is the potential for a positive experience connecting with other youth and young adults.

Incentives: You will receive $20 for each of the four interviews that you provide, for a total of $80. There are no incentives for participation in the individual counseling sessions or in groups.

Authorization to Use Protected Health Information: The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared outside of The Institute for Community Living. This document will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI, and in what ways they can use the information. In order for the Principal Investigator Michelle Munson, and the research study staff to collect and use your PHI, you must sign this authorization form. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on treatment at Jewish Board.

By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below. The researchers working on this study will collect the following PHI about you: the frequency with which you attend all appointments at The Institute for Community Living clinic and your current diagnosis. This PHI will be used to understand whether there is a difference in attendance between adolescents in the Just Do You group versus the Best Available Treatment group.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Michelle Munson, New York University Silver School of Social Work, 1 Washington Square North, New York, NY 10003.

If you have a complaint or concerns about the privacy of your health information, you may also write to The Institute for Community Living (ICL) at 125 Broad Street, New York NY 10004. Complaints should be sent within 180 days of finding out about the problem. The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this authorization and as directed by state and Federal law. ICL is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of ICL, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information. By signing this document, you agree for ICL to disclose to the research staff as part of the Just Do You research project at New York University Silver School of Social Work your protected health information as specified above.

Contact Questions/Persons: If there is anything about the study or your participation that is unclear or that you do not understand, or if you have questions or wish to report a research related problem, you may contact Michelle Munson by phone at 212-992-9731, or e-mail at mm5174@nyu.edu. For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects, New York University, 212-998-4808 or ask.humansubjects@nyu.edu. You will receive a copy of this consent.

Statement of Consent: "I have read the above description of this research and I understand it. All my questions have been answered to my satisfaction. I voluntarily agree to participate in this study"

Permission to Participate

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date Signed
_____	_____	_____
Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date Signed

Permission to Share Data with NIMH

Data from this study may be submitted to the National Institute of Mental Health (NIMH) Data Archive (NDA) that allows researchers studying mental illness to share deidentified information with each other.

All names and personally identifying information, are removed from the data set before submitting it. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly. Although you may not benefit directly from allowing your information to be shared with NDA, the information provided to NDA may help researchers learn how to treat future children and adults with mental illnesses so that they have better outcomes.

Experts at the NIMH who know how to protect health and science information will screen every future data sharing request carefully to help ensure your privacy is protected. If you decide later that you do not want to share your information using NDA, you can contact us at any time and we will tell NDA, which will then stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. Again, there will be no identifying information associated with your data.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date Signed

_____	_____	_____
Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date Signed