Study Consent to Participate

Mental Health Treatment Study (MHTS)
Sponsored by the Social Security Administration (SSA)

I _____ consent to participate in the Mental Health Treatment Study (MHTS), sponsored by the Social Security Administration (SSA) Office of Program Development and Research. The purpose of this study is to learn more about mental health treatment and vocational programs for Social Security Disability Insurance (SSDI) beneficiaries who have a primary impairment of schizophrenia or affective disorder and want to work. By consenting to participate in this study I agree to willingly participate in the following study components over the next 24 months:

- An interview about my health and work history at the beginning of the study;
- Brief interviews about my health and work history once every three months; and
- A followup exit interview about my health and work at the end of the 24-month period.

After the first interview, I will be randomly assigned to one of two groups, either the **Treatment Group (Special Services)** or the **Control Group (Regular Services)**.

If I am assigned to the **Control Group (Regular Services)**, study staff will provide me a packet of information about health care and vocational programs available in my community. Study staff will also pay me $20.00 for the first interview, and $10.00 for each quarterly interview and the followup exit interview, for a total of $100 if I complete all the interviews.

If I am assigned to the **Treatment Group (Special Services)**, I agree to participate in all study components over the next 24 months, including:

- Complete psychiatric assessment within one week of enrollment;
- Complete medical physical exam within one month of enrollment;
- Working with my doctor to evaluate and manage my medication, if needed;
- Supported employment services;
- Individualized behavioral treatment (if I, the study team, and my doctor feel it would be helpful to me); and
- Receive health insurance for my prescription medication and medical care[1] that is eligible for coverage under the MHTS (study will pay the health insurance premiums).

If I am assigned to the Treatment Group (Special Services), all of the study services eligible under the MHTS will be provided to me free of charge, but at the end of the two years, the study will no longer pay for any of these services, including my medicine, health care, supplemental insurance or supported employment services. However, as I approach the end of the two-year period, study staff will work with me, my study team, and my doctor to prepare a transition plan for me. This transition plan will help me to continue to receive the medicines and services I need through other

[1] This includes payment for hospitalization up to $50,000 per year for portions of care not covered by insurance.

programs after the study ends. However, there is no *guarantee* that all my medicines and services will be continued after the end of the study.

If I am assigned to the Treatment Group (Special Services), SSA will postpone doing a Medical Continuing Disability Review (CDR) of my medical eligibility for SSDI benefits for up to 24 months while I am enrolled in the study, as well as for 12 months after I leave the study. Medical CDRs initiated before my enrollment in the MHTS cannot be postponed.

My participation in this study is voluntary. I do not have to take part in this study. If I do not participate in the MHTS study, there will be no penalty, and I will not lose SSDI benefits. I can stop participating in the study at any time. There is no penalty for dropping out whenever I choose; however, the benefits to me for participating in the study will then stop.

There are no apparent risks for participating in the MHTS. Just being part of the study will have no effect on my SSDI benefits. However, there are two ways that my SSDI benefits may be affected in the future if I participate:

1. If I decide to begin working, my SSDI benefits may be affected. However, a benefits counselor will work with me during the study so that I will know exactly how work might affect my SSDI benefits.

2. My health may improve as a result of my getting services through the study. My improved health may lead to better life functioning and work, which may affect my eligibility for SSDI benefits.

Some study interviews or assessments may be audio-recorded for the purpose of quality control. I will always be asked to give permission for such recordings, and I can refuse to have any interview or assessment audio-recorded. The audio recordings will only be reviewed by supervisors. SSA will not have access to these audio recordings.

Information collected about me for this study will be kept private and confidential and is protected by law according to Section 1106 of the Social Security Act (42 U.S.C. 1306) and the Privacy Act (5 U.S.C. 552a). My information will be used solely for the purposes of this research and will not be released to non-research study staff except as required by law. The Social Security Administration (SSA) Office of Program Development and Research will not share any information about me from this study with any other offices at SSA. I can ask questions about the study and receive answers that I can understand. [SUBCONTRACTING CENTER] staff has explained to me my rights and responsibilities under the study and has given me a copy of this form. By signing this consent form I have not waived any of the legal rights that I otherwise would have as a participant in a research study.

CONSENT SIGNATURE:

_____
Beneficiary Name (please print)

_____ _____
Signature of Beneficiary Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

----------Use the following only if applicable ----------

If this consent form is read to the beneficiary because the beneficiary is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to and apparently understood by the beneficiary. The beneficiary freely consented to participate in the research study.

_____ _____
Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling beneficiaries who do not speak English.

The information we collect in this study is in accordance with the clearance requirements of Section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid control number from the Office of Management and Budget (OMB) in the Federal government. The OMB Control Number for this collection is 0960-0726, expiration date 7/31/2009.

FOR OFFICE USE ONLY Study ID # _____ Provider ID #: _____

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Frequently Asked Questions about the MHTS

We invite you to participate in the Mental Health Treatment Study (MHTS), an important national study sponsored by the Social Security Administration (SSA) Office of Program Development and Research. In order to give us your permission to participate in the MHTS, there are three important consent forms enclosed in this booklet that we ask you to review and sign. As you read this booklet, if you have any questions about the study or the consent forms, please ask us. Do not sign these forms unless you are completely comfortable with their content. Below are the answers to some frequently asked questions that will give you more information about the MHTS.

Why is the SSA doing this study?

SSA is doing this study to learn if providing certain Social Security Disability Insurance (SSDI) beneficiaries with better access to medical treatment and vocational services will help them to find good jobs they want and function better overall in their daily lives. SSA also wants to learn more about the kinds of treatments and services that work best for beneficiaries and the costs of these treatments and services.

Why is this study important?

Many SSDI beneficiaries want to have jobs that interest them and lead healthier lives, but cannot because they are unable to get the health care, medicines or vocational support they need. This study will find out how SSA can best provide beneficiaries with the help they need. If this study is successful, then SSA will consider making important policy changes to their programs in order to better support SSDI beneficiaries like you.

Who is conducting this study?

The Social Security Administration (SSA) is sponsoring this study. SSA has agreements with Westat, a national research company, and with local doctors and vocational programs that will conduct this study.

What is Westat?

Westat is an employee-owned research organization headquartered in Rockville, Maryland. Westat has 45 years of experience conducting large health-related research projects for many agencies of the U.S. Government, including SSA.

Why did you choose me to participate in this study?

SSA provided us with a list of people who currently receive SSDI benefits and have been diagnosed with certain psychiatric disorders. We randomly selected your name from this list. We will randomly select a total of 3,000 SSDI beneficiaries in 22 cities throughout the U.S. to participate in the MHTS.

Do I have to participate in the MHTS?

No. This is an important national study and we hope you will want to participate, but participation in the MHTS is completely voluntary. It is totally up to you.

If I decide not to participate in the MHTS, will my SSDI benefits be affected?

No. There is no penalty for choosing not to participate, and your SSDI benefits will not be affected if you decide not to participate.

What do I have to do to participate in this study?

If you decide to participate in this study, the first thing we will ask you to do is answer a few questions to confirm your eligibility for the study. Next, we will ask you to carefully read and sign two different consent forms that describe in detail how you will participate and what kinds of information we will collect about you. Once you sign these consent forms, study researchers will begin collecting important information about you for the study. These two consent forms are as follows:

- Consent form indicating you agree to participate in the study
- SSA Form-3288 authorizing SSA to release your information from SSDI files to the MHTS researchers

Do I have to sign these two consent forms?

No. You can choose not to sign the consent forms. However, you will not be able to participate in the study and receive its benefits unless you sign both consent forms.

Will you ask me to sign any other forms?

If you live in the State of Maryland, we will ask you to sign a Consent for Release of Earnings Information. However, you are not required to sign this form in order to continue to participate in the study. If you are later assigned to the Treatment Group (Special Services), we will also ask you to sign an Authorization and Request for Release of Medical Records form.

What happens after I sign the consent forms?

Once you sign both consent forms, we will interview you for about 25-30 minutes, asking you questions about your health, work history, and related topics. After that, information about you will be sent to Westat's home office in Rockville, Maryland. There, a computer will randomly assign you to one of two study groups: the Control Group (Regular Services) or the Treatment Group (Special Services).

What happens if I am assigned to the Control Group (Regular Services)?

If you are assigned to the Control Group (Regular Services), every three months for the next two years we will call and ask you to participate in a 5 to10 minute telephone interview to update your contact information and to ask about your employment status and any services that you have received. We will also provide you a packet of information about health care and vocational programs (i.e., programs that will help you to find and keep a job) that you can apply for in your community. At the end of the two-year period, we will also ask you to participate in a 25 to 30 minute followup interview about your health and work. We will pay you $20.00 for the first interview you have with us and $10.00 for each quarterly interview and the followup exit interview, for a total of $100 if you complete all the interviews.

What happens if I am assigned to the Treatment Group (Special Services)?

If you are assigned to the Treatment Group (Special Services), we will ask you to sign a third consent form called the Authorization and Request for Release of Medical Records. If you have had more than one health care provider over the past two years, we may ask you to sign one of these forms for each provider.

Over the next two years you will be provided with:

- Supported employment services that are designed to help you find a job that is consistent with your preferences, skills and experiences;
- Individualized behavioral and mental health treatment that will support you in your work efforts;
- Assessment of mental and physical health;
- Help from a doctor to evaluate and manage medications, if needed;
- Assistance from a nurse care coordinator who will oversee services that you are receiving to be sure they are of high quality;
- Health insurance to supplement your current coverage for behavioral health costs[2] and the cost of needed medications.

In addition, SSA will postpone conducting a Medical Continuing Disability Review (CDR) to determine your medical eligibility for SSDI benefits for the 24 months while you are enrolled in the study, and for an additional 12 months after you leave the study. If SSA initiated a Medical CDR **before** the date you enroll in the study, the Medical CDR cannot be postponed. If you withdraw from the MHTS early, the postponement of the Medical CDR will be suspended and you may receive a Medical CDR.

[2] This includes payment for hospitalization up to $50,000 per year for portions of care not covered by insurance.

If I am assigned to the Treatment Group (Special Services), will I have to pay for my medication, health care and other services that I receive by participating in the study?

No. You will not have to pay for any medical health care or vocational/behavioral costs that you receive through participating in the MHTS and that are considered eligible under the MHTS. The study staff will tell you before you enroll in the study what costs are eligible. If you do not have health insurance, the study will provide you with health insurance that will pay for eligible services. If you already have health insurance, the study will provide you with supplemental insurance to cover any eligible costs not already covered. We will also reimburse you for all copayments and transportation costs to and from the places where you receive services during the study.

If I am in the Treatment Group (Special Services), what happens to me at the end of the two year study period?

At the end of the two years, the study will no longer pay for your medicine, health care, supplemental insurance, or supported employment services. However, study staff will work with you, your treatment team, and your doctor to prepare a transition plan for you as you approach the end of the two-year period. This transition plan can help to ensure that after the study ends you can continue to receive the medicines and services you need through other programs. But, there is no *guarantee* all of your medicines and services will be continued. By the end of the two-year period, you will be eligible to receive Medicare, which will cover some of your health care costs. As a result of your participation in this study, you may also be working at a job that provides health insurance benefits.

What information will you collect about me during the next two years?

If you choose to be in this study, the study researchers will request personal information about you. Through study interviews, researchers will request information about your SSDI benefits and your health and employment history.

If you are assigned to the Treatment Group (Special Services), additional information obtained about you during the study may include:

- The diagnosis and treatment of mental health conditions
- HIV/AIDS
- Hepatitis infection
- Sexually transmitted diseases
- Other reportable infectious diseases
- Physical exams
- Laboratory, x-ray, and other test results
- Information contained in records about any medications you received
- Medical billing and insurance information

Will any of my interviews or assessments be audio- or video-recorded?

Some study interviews may be audio-recorded for the purpose of quality control. You will always be asked to give permission for such recordings, and you can refuse to have any interview audio-recorded. No one at SSA will hear these audio recordings, and the recordings will be destroyed as soon as the study supervisors have finished reviewing them. You will not be video-recorded.

Will information about me be kept private and confidential?

Yes. Your study information will be kept private and confidential and is protected by law according to Section 1106 of the Social Security Act (42 U.S.C. 1306) and the Privacy Act (5 U.S.C. 552a). However, in very rare cases according to the law, such as if your study doctor suspects you may harm yourself or others, your confidentiality may not be kept.

Who may use and give out information about me?

Information collected about you during this study may be used by your doctors, employment counselors, and the study researchers. These individuals may see the research information during or after the study. The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

Will the SSA Office of Program Development and Research share my study information with any other offices at SSA?

No. The SSA Office of Program Development and Research will use your information solely for the purposes of this research study. No information will be shared with any other offices at SSA.

Will my SSDI benefits be affected if I participate in this study?

Just being part of the study will have no affect on your SSDI benefits. However, there are two ways that your SSDI benefits may eventually be affected if you participate:

1. If you decide to begin working, your future SSDI benefits may be affected. However, a benefits counselor will work with you during the study so that you will understand exactly how work might affect your benefits.

2. As the result of your participation in this study, your health and functioning may improve. SSA may learn about your improved health status by talking to you and/or your doctors or by requesting your medical records during your next CDR. Your improved health may then affect your eligibility for future SSDI benefits.

What if I decide not to give permission to use and give out my health information?

By signing the consent forms, you are giving permission to use and give out the health information listed above for the purposes described. If you refuse to give permission, you will not be able to participate in the MHTS.

May I review or copy the information obtained from me or created about me?

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

Can I withdraw my permission and stop participating in the study?

Yes. You can drop out of the study at any time by writing to the MHTS Westat contact person listed at the end of this booklet. There is no penalty for dropping out whenever you choose. However, the services and other benefits offered through the study will then stop, and CDRs for Treatment Group (Special Services) participants can no longer be postponed.

Can I withdraw my permission to use and disclose the information you collect about me for the study?

Yes. You may withdraw or take away your permission to use and disclose your study health information at any time. However, your permission will not stop automatically. The use of your personal information will continue until you cancel your permission in writing to the MHTS Westat contact person listed at the end of this booklet. If you withdraw your permission, you will not be able to continue in this study. When you withdraw your permission, no new health information which might identify you will be gathered after that date. If the study researchers still need your information, your information that has already been gathered may still be used and given to others. If you withdraw your permission, all of your study benefits will also end.

Can I ask questions about the study?

Yes. You may ask any questions about the study at any time, and you are entitled to receive answers to your questions that you can understand. You may direct your questions to your study nurse Care Coordinator or to the MHTS Westat contact person listed at the end of this booklet.

Who do I contact if I have questions about the study?

If you have any questions about this study or your participation in this study, if you wish to withdraw from the study, or if at any time you feel you have experienced a research-related injury or a reaction to a medication you received during the study, you may contact:

Hilary Kruger
Westat
1650 Research Blvd.
Rockville, MD 20850
1-888-580-9932 or 301-738-3579

If you have questions about your rights as a research subject, you may contact:

Carol Haines
Administrator, Westat Institutional Review Board
Westat
1650 Research Blvd.
Rockville, MD 20850
1-800-937-8281 or 301-738-8388

BURDEN STATEMENT

OMB Control Number: 0960-0726 Expiration Date: 07/31/09

Public reporting burden of this collection of information is estimated to average 1.9 hours per year per Treatment Group (Special Services) participant and 1 hour per year per Control Group (Regular Services) participant, including the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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