Caregiver Informed Consent – Young Adult Informed Assent
Common Study

Title of Research Project:	VCHIP Evaluation of the Vermont Children's Mental Health Initiative
Principal Investigator:	Judith Shaw, RN, MPH, EdD
	Vermont Child Health Improvement Program University of Vermont N329 Courtyard at Given 89 Beaumont Ave. Burlington, VT 05405 (802) 656-8210
Sponsors:	US Department of Health and Human Services (DHHS) and the Vermont Department of Mental Health

Please note: Throughout this document, "you" refers to you and your young adult.

You are being invited to take part in this research study because your young adult is receiving mental health and/or related services in his or her local community. This research study is being conducted by the VCHIP at the University of Vermont's College of Medicine.

We encourage you to ask questions and take the opportunity to discuss the research study with anybody you think can help you make this decision.

Why is this research study being conducted?
Your community is participating in a national effort to improve services and supports for young adults and their families. The goal of this project is to give young adults who are experiencing emotional and behavioral problems and their families the necessary supports to have successful and healthy lives. This effort is being paid for by the Center for Mental Health Services in the United States Department of Health and Human Services (DHHS). The University of Vermont is conducting a research study of these services to look at whether the quality of services and the lives of young adults and their caregivers receiving those services have improved.

How many people will take part in the research study?
Over the next 5 years, we expect approximately 1500 young adults and their caregivers will take part in this research study.

What is involved in the research study?
The purpose of this research study is to look at how the lives of young adults participating in a system of care and the lives of their families improve based on the services they receive. A system of care is a way of meeting young adults' mental health and related needs. It is based on the idea that the mental health and related needs of young adults and their families can be met by a coordinated approach within their community.

We will ask you questions about your overall functioning, including mental health and substance use, and your experience with the services you receive. If you consent to participate in this research study, we will collect the following information from your clinical record: mental health diagnosis; demographic information including date of birth, gender, race, ethnicity, and zip code; and service enrollment information including social service agency involvement (types of social service agencies with which you are involved), referral source, reason for referral, service planning participant roles/agencies (not names of individuals), coverage type and source.

We will ask to get information from you up to 5 times—every 6 months until 2 years from now. We will obtain this information through a combination of looking at your records and asking you questions. In most cases, interviews will be conducted by someone who works in the system of care. However, in the unlikely event this is not feasible, one of the UVM evaluators will conduct the interview. The first interview will occur today or within the next week. We will contact you again in 6, 12, 18, and 24 months to obtain the same information from you, if you are still receiving services at those points. If you are no longer receiving services, we will not contact you. Interviews will be conducted in person at the time of your existing service appointment, wherever that appointment might occur.

If you reach age 18 at any time during this project, we will ask you to complete a consent form for individuals 18 years of age or older.

What are the risks and discomforts of the research study?
It is possible answering questions about personal matters and the services you have received may be uncomfortable. You have the right to refuse to answer any question and to quit the study at any time.

You may be worried information about you will be shared with people outside of the researchers. With every research study, there are potential risks of breaching confidentiality. We have taken steps to protect the confidentiality of information gathered about you. These steps are described below under "What About Confidentiality."

What are the benefits of participating in the research study?
There are no direct benefits to you for being part of this study. You may learn new things about yourself and the service system. As a result of this project, services may get better for young adults with mental health and/or related needs and their families.

Are there any costs?
The only cost associated with participating in this research study is your time. You will be asked to commit about 15 minutes for each of the five meetings – initial, 6-month, 12-month, 18-month, and 24-month.

What is the compensation?
There is no compensation for participating in this research study.

Can you withdraw or be withdrawn from this research study?
Your participation is voluntary. If you agree to be part of this research study, you can change your mind and quit at anytime. If you quit the research study, any information you gave will be destroyed if this is what you want. If you decide not to participate in the research study, it will not affect services for you and your family now or in the future.

What about confidentiality?

We have taken steps to protect your privacy. All information about you will be kept confidential except for specific situations listed below. Only authorized people will have access to the information. None of the interview forms will have your name on them. They will only have special codes. Any papers with your name on them will be kept in a locked filing cabinet. When we finish interviews and are traveling back to our office, we will make sure your information stays with us at all times and/or is in a locked car. In reports, your answers will be grouped with those of others.

The information you provide, or that we access from organizations providing services to you, may be reviewed only by authorized staff that work with the services for transition-aged youth project as well as the Institutional Review Board for verification of research procedures and/or data.

Findings from this evaluation will be shared in Vermont in regional and statewide reports. The results of this research study may eventually be published and information may be exchanged between other investigators. We will maintain your confidentiality in all reports and publications by combining your responses with those of other people. We will never mention your name(s) in any reports, or any information that may identify you.

As we mentioned above, this research study is part of a national effort to improve systems of care. To help with that, we are required to send information about you to the Department of Health and Human Services through a secure website to be combined with information on others data collected from around the country. All information that could identify you will be removed before it is sent to DHSS.

To provide even more protection, we obtained a Confidentiality Certificate from the Federal government to protect the researchers, including the people who interview you from being forced, even under a court order or subpoena, to identify you. It adds special protection to the **research** information about you. An exception to this Confidentiality Certificate is if we learn about child abuse or neglect or if you tell the interview staff you plan to harm yourself or someone else (see next paragraph). In addition, the Department of Health and Human Services (DHHS), the Federal agency funding this research, may see your information if it audits us. The Confidentiality Certificate does not imply the government, DHHS, has approved or disapproved of this review.

There are two exceptions to confidentiality: If we become aware of child abuse or neglect, we must report it to the Child Protective Services. If we are concerned you might hurt yourself or someone else, we must report it to authorities. This is done to protect the person who might be hurt. Should the evaluator(s) feel a duty to report information under these two areas, we would discuss the need to report with you first unless doing so posed imminent risk. We would work with you to help you find resources to appropriately address these concerns.

Contact Information

You may contact Dr. Judith Shaw, the Principal Investigator, at 802-656-8210 for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe you have been injured as a result of your participation in this research study you should contact Nancy Stalnaker, the Director of the Research Protections Office at the University of Vermont at 802-656-5040.

Statement of Assent

I have read this form or it has been read to me and I understand what it says. My questions (if any) have been answered. A copy of this form will be given to me. By signing my name below, I freely agree to be in the project.

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Minor Providing Assent Date

This form is valid only if the Committees on Human Research's current stamp of approval is shown below.

_____

Name of Minor Providing Assent Printed Date of birth

Statement of Consent

- ☐ You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below.
- ☐ Participation is voluntary, and you may refuse to allow your child to participate or withdraw your child at any time without penalty or prejudice.
- ☐ You agree to allow your child to participate in this research study and you understand that you will receive a signed copy of this form.

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Signature of Legal Guardian or Legally Authorized Representative (applicable for children and subjects unable to provide consent) Date

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Name of Legal Guardian or Legally Authorized Representative Printed

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Signature of Principal Investigator or Designee Date

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Name of Principal Investigator or Designee Printed

Name of Principal Investigator: Judith Shaw, RN, MPH, EdD,

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Committee on Human Research
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