Appendix B:

INFORMATION SHEET AND INFORMED CONSENT FORM

Caregiver Version

Title of Research Study:
Among at-risk youth with mental health challenges, do integrated collaborative care teams provide more benefits in reducing symptoms, improving functioning and providing greater client satisfaction than treatment as usual?

Principal Investigator:
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What is the purpose of this study?
This study is investigating the impact of integrated collaborative care for youth, compared to the usual treatment provided by CAMH. We want to find out if one of two treatment pathways is more effective than the other in (1) helping youth improve their symptoms and functioning, (2) satisfying youth and caregivers, (3) reducing the cost to the healthcare system.

What will I be asked to do as part of this study?
If you decide to participate in this study, you will be asked to do the following:

First assessment: All caregivers will attend a 1.5 hour meeting to consent to the study and complete assessments about their youth using questionnaires. The questionnaires will cover topics such as demographic characteristics, youth symptoms, youth functioning, and caregiver burden. Questionnaires will be given using the RedCap software, which is a secure, encrypted software for research data collection.

Second assessment: All caregivers will take part in a telephone interview within approximately one week of the first assessment. The interview will be about their youth for about 1-2 hours. The purpose of the interview will be to give the caregiver the opportunity to describe their youth more in depth. The interview may be recorded to establish reliability, only to be heard by the research team.

Services: After the first research meeting, all participating youth and caregivers will be randomly assigned to one of two service pathways: an integrated collaborative care team in the community or usual CAMH services. They will then meet with their new clinicians and receive the services selected for them. Integrated collaborative care will involve referral to a community mental health agency offering a variety of mental health and addiction services for youth and their caregivers. The usual hospital services will involve consultation with a professional at CAMH and the services selected by that professional.

Six-month and twelve-month assessments: After six months and again after twelve months, participating caregivers will be assessed again. The questionnaires will include some of the same evaluations conducted at the beginning of the study, as well as questions about satisfaction and service use.

What is the study eligibility?
To participate in this study, you must be the primary caregiver of a youth who has recently been referred to CAMH, be eligible to receive out-patient services at CAMH for mental health and/or addiction issues, and be between 14 and 18 years of age. As the caregiver participant, you must be a primary caregiver of the youth and

be aware of the youth's everyday experience. Both you and your youth must also be able to consent to participate in this study and be able to read and write in English.

What are the risks or harms of participating in this study?

We expect that you will experience minimal discomfort from participating in this study. Full services will be provided in both treatment groups. However, answering the assessment questions may cause discomfort for some people due to sensitive questions of a personal nature. If you or your youth feel discomfort and wish to discuss it, the Research Assistant will help connect you to a mental health professional.

What are the benefits of participating in this study?

By participating in this study, you will be contributing to invaluable research by expressing a caregiver's perspective. All participants will help provide information that will benefit future patients by helping to shape the services offered to youth and their families.

Can participation in this study end early?

You can choose to end your participation at any time without having to provide a reason. If you choose to withdraw, your youth can continue to participate in the study and/or to receive treatment. If you withdraw your consent, the information acquired from you will still be used; however, no additional information about you will be acquired. However, if you request, all previous information will also be destroyed. In addition, the investigators or their staff responsible for this study may end your participation at any time, at their discretion.

What are the costs of participating in this study?

Participation in this study will not involve any additional costs to you.

Are study participants paid to participate in this study?

Participants will receive an honorarium for taking part in this study. As a participating caregiver, you will receive a $25 gift card after completing the first two assessments, then $25 after each of the third and fourth assessment, as well as entry into a random draw for an additional $250 (gift card).

How is confidential information handled?

The person accessing your youth's file or contacting you must maintain your confidentiality to the extent permitted by law. For example, the law could make us give information about you if a child has been abused. Only members of the research team will have access to your information. Your name, your youth's name, and any other personal identifiers will not be used in any reports or publications arising from this study. You will be assigned a confidential code number. As part of the quality assurance review of this research project, your study records might be assessed on behalf of the Research Ethics Board. A person from the CAMH research ethics team may contact you to ask questions about the research study and your consent to participate.

As part of the Research Services Quality Assurance Program, this study may be monitored and/or audited by a member of the Quality Assurance Team. Your research records and your youth's research and CAMH records may be reviewed. During this process, confidentiality will be maintained as per CAMH policies and the extent permitted by law.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

More information

You have the right to receive all important information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant.

If you have any further questions at any time, please feel free to contact **Dr. Lisa Hawke, Ph.D., Project Coordinator, at 416-535-8501 ext. 39026**, or Dr. Peter Szatmari, M.D., Qualified Investigator at 416-535-8501 ext. 34029. If you have any questions about your rights as a participant in a research study, you may contact **Dr. Padraig Darby, Chair, Research Ethics Board, Centre for Addiction and Mental Health, at 416-535-8501 ext. 36876**.

CONSENT TO PARTICIPATE

Study Title: Among at-risk youth with mental health challenges, do integrated collaborative care teams provide more benefits in reducing symptoms, improving functioning and providing greater client satisfaction than treatment as usual?

Name of caregiver participant: _____

I, _____, have read (or had read to me) the Information Sheet for the study named above. My questions, if any, have been answered to my satisfaction.

I consent to participate in the study. I have been given a copy of this form to keep.

☐ I agree to be contacted for future studies at the contact number provided for this study.

☐ I do not agree to be contacted for future studies.

Caregiver Participant: Name (print) _____

Date (yyyy-mm-dd) _____

Signature _____

Person Obtaining Consent: Name (print) _____

Date (yyyy-mm-dd) _____

Signature _____