INFORMED CONSENT FORM – PARTICIPANT

Study Title: A Study of Cognitive Adaptation Training in Inpatient Forensic Environments

Responsible Investigators: Sean Kidd 416-535-8501 ext. 6295, Centre for Addiction and Mental Health (CAMH); Courtney Brennan, CAMH; John Spavor, CAMH; Stephanie Penney, CAMH; Riley Saikaly, University of Toronto; Kerri Adams, University of Toronto.

INTRODUCTION

You are being invited to participate in a feasibility trial (a type of study that involves research). You are invited to participate in this trial because your treatment team believes you may benefit from an intervention called Cognitive Adaptation Training. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with others.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Your choice to not participate or your choice to withdraw **will not** affect any treatment needs that you might have at the Centre for Addiction and Mental Health now or in the future.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Some people with a psychosis diagnosis may have difficulties with cognitive functioning. Cognitive functioning refers to abilities such as attention, memory, and problem-solving. These difficulties have been shown to impact peoples' adaptive functioning (e.g., getting a job, going back to school, etc.). An intervention called Cognitive Adaptation Training has been shown to be helpful with these issues.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if the intervention of Cognitive Adaptive Training can be adapted to better meet the needs of patients within a forensic inpatient setting, including helping clients like you reach goals related to organizing your space or managing your personal hygiene.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care. You will continue to receive treatment as usual from your regular treatment team should you chose to not participate. You do not have to take part in this study. If you choose not to participate in this study, CAT will still be avaialble to you as an intervention at a later date.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 24 people will take part in this study. This study should take 6 months to complete and the results should be known in about a year.

WHAT IS THE STUDY INTERVENTION?

Cognitive Adaptation Training involves a CAT clinician visiting you in your room on the unit for around 30 minutes twice a week to establish routines that we hope may help you to achieve your goals. They may do things like set alarm clocks, fill in weekly calendars, and help organize your living space.

As a participant in this study, you will take part in cognitive adaptation training. You will receive the interventions described above for 4 weeks. For the following 2 months, staff from your unit will help you maintain the new skills and routines. This study will involve research.

WHAT ARE THE STUDY PROCEDURES?

As a part of this study, you will participate in the following:

1. Before the intervention starts you and your treatment team will be asked questions about your day-to-day functioning, if appropriate.

2. You will participate in the 3-month program of Cognitive Adaptive Training, as described in the section above.

3. At the end of the first 4 weeks of CAT, you and your treatment team will complete another set of questions about your day-to-day functioning. These questions will be the same as the ones asked before the intervention started. (See #1).

4. 2 months after you have finished the CAT intervention, you and your treatment team will be asked to answer the same questions you completed in steps #1 and #3.

5. Following the intervention follow-up, you will be asked to attend an individual feedback session. Each individual feedback discussion will be one session lasting approximately 30 minutes and will take place on your unit at CAMH. You will be asked to speak about your experiences with the intervention. This information will be kept confidential and your responses will not impact your treatment at CAMH in any way. The focus group sessions may be audiotaped with your permission.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Make best efforts to be present on the unit for your scheduled appointments
- Allow the Cat Clinician working with you into your room to help you organize the space

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study length is 5-6 months (depending on procedures). The study intervention will last for about 3 months.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff. You may withdraw your permission to use information that was collected about you for this study at any time by letting the study doctor know. However, this would also mean that you withdraw from the CAT intervention.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, without your consent, for reasons such as:

- The study intervention does not work for you
- You are unable to tolerate the study intervention
- You are unable to complete all required study procedures

Research personnel may withdraw you from the study early if the researchers do not think it is in your best interests to continue. Research personnel will discuss the reasons for the withdrawal with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

We do not anticipate there being any physical discomfort related to you participating in this study. While psychological risk is expected to be minimal, some aspects of the intervention involve working in your room on the unit. The CAT Clinician may ask to see or talk about different areas of your room throughout the intervention. This has the potential to feel like an invasion of privacy, or lead to the discovery of contraband. Your explicit verbal consent will be asked before accessing any part of your room, and you will always be given the opportunity to say no. Any contraband discovered will be reported to your treatment team. All participants are encouraged to discuss any experienced distress with the research assistant. Opportunities will be made for you to access support through your Unit Staff and Psychiatrist if necessary.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Participation in this study may result in you developing strategies that will allow you to compensate better for any cognitive difficulties you experience. It might also lead to you being better able to manage your illness independently. Additionally, your participation may assist in the development of cognitive adaptation training programs that could be accessed by other persons with mental illness.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study.

A delegated Research Coordinator will access personal health information (PHI) to confirm your eligibility to participate in the research study. No PHI will be collected for this purpose. .

All information that identifies you will be kept confidential and stored and locked in a secure place that only authorized CAMH personnel will have access to. In addition, electronic files will be stored on a secure hospital or institutional network and will be password protected. The investigators will dispose of your paper and computer-based records after the research obligations for the study have been met. Confidentiality will be respected and no information that discloses your identity will be released or published without consent unless required by law. The information you provide will not affect the usual care that you receive.

Authorized representatives (e.g. monitor(s), auditor(s), IRB/IEC, and the regulatory authorities**)** of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, records for verification of clinical trial procedures and/or data, without

violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing this form, you authorize such access.

- The Centre for Addiction and Mental Health
- The Research Ethics Board (REB) who oversees the ethical conduct of this study in Ontario

All records identifying you will be kept confidential to the full extent provided by law and will not be disclosed or made publicly available, except as described in this consent document. In addition, neither your name nor any other personal identifier will be used in any reports or publications arising from this study. You should know that there are three exceptions to our confidentiality policy. In any of the following situations, we are obligated by law to contact authorities: 1) if there is a serious possibility that you may harm yourself or others, 2) if you have been involved in any form of child abuse or neglect, 3) if you have been the victim of abuse by a healthcare worker. As part of the Research Services Quality Assurance role, this study may be monitored and/or audited by the Quality Assurance Team. Your research records and CAMH Records may be reviewed during which confidentiality will be maintained as per CAMH policies and to the extent permitted by law.

Client-specific research data gathered as part of this study may be shared and provided to the participant's unit treatment team for client care.

It is of note that your participation in this study will be recorded in your health record at CAMH and a copy of your consent will be added to the health record.

With regards to the focus group, while the study team will take precautions to protect your confidentiality we cannot guarantee that other members of the focus group will respect your privacy or keep the discussions of the group confidential.

WHAT HAPPENS TO STUDY RESULTS?

After the data from the study has been analyzed, a report will be submitted to an academic journal. The data that you provide in your assessments would be anonymized (all identifiers removed like name, age, gender). This protects your privacy and also helps ensure that readers are fully informed about the trustworthiness of the research that has been done.

WHAT IS THE COST TO PARTICIPANTS?

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

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

If you decide to participate in this study, you will receive $10 value in gift cards from Gifts of Light or Stamp Store stamps depending on your preference.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please let the research staff know. Your rights to

privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

If you have questions about the study that are not answered in these Information Sheets, please ask them. In addition, if you have questions in the future you may contact the study investigators at the telephone numbers given on the first page.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the doctor who is in charge of the study at this institution. That person is:

Sean Kidd	416-535-8501 ext. 6295
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Research participants may contact Dr. Robert Levitan, Chair, Research Ethics Board, Centre for Addiction and Mental Health, to discuss their rights. Dr. Levitan may be reached by telephone at 416-535-8501 ext. 34020.

Robert Levitan	416-535-8501 ext. 34020
Name	Telephone

AGREEMENT TO PARTICIPATE

I, _____, have read (or had read to me) the Informed Consent Form for the study named 'A Study of Cognitive Adaptation Training in Inpatient Forensic Environments.'

- My role in the study is as a research volunteer to help the investigators see if modifications can be made to CAT to make it more appropriate to a forensic inpatient setting
- All of my questions have been answered.
- I understand the information within this informed consent form.
- I do not give up any legal rights by signing this consent form.
- I agree to voluntarily participate in this research and give my consent freely.
- I understand that the project will be conducted in accordance with the Informed Consent Form, a copy of which I have retained for my records.
- I understand I can withdraw from the project at any time, without penalty, and do not have to give any reason for withdrawal.
- I allow access to medical records and related personal health information as explained in this consent form.
- I understand that my inpatient treatment team will be informed of study participation.

I consent to:

- Complete an assessment about my day-to-day functioning
- Participate in 4 weeks of cognitive adaptation training
- At the end of the 4 weeks, complete another assessment about my day-to-day functioning
- Following the second assessment, allow 2 months of unit staff follow-up on the learned skills from the intervention.
- At the end of the 2 months of unit staff follow-up, complete another assessment about my day-to-day functioning
- Following the third assessment, attend 1 individual feedback session (about 30 minutes in length) on my unit at CAMH that may be audiotaped with my permission.
    - Please select if we have your permission to audio record your responses during the individual feedback session (check ONE box):
        - ☐ You have my permission to audio record my responses during the individual feedback session
        - ☐ You *do not* have my permission to audio record my responses during the individual feedback session.
            - Please select if you would like an individual interview to provide feedback that is *not* audio recorded instead (check ONE box):

- ☐ I would prefer an individual interview
- ☐ I would *not* prefer an individual interview and, therefore, will not participate in providing feedback.

Please note that you are welcome to change your mind the day of the individual feedback session by notifying a member of the research team.

_____	_____	_____
Signature of Participant	PRINTED NAME	Date

_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

If the participant does not have the capacity to consent:

As a Substitute Decision Maker (SDM), you are being asked to provide informed consent on behalf of a person who is unable to provide consent for him/herself. If the participant gains the capacity to consent for him/herself, your consent for them will end.

I, _____, have read (or had read to me) the Informed Consent Form for the study named 'A Study of Cognitive Adaptation Training in Inpatient Forensic Environments.'

- The participant's role in the study is as a research volunteer to help the investigators see if modifications can be made to CAT to make it more appropriate to a forensic inpatient setting
- All of my and the participant's questions have been answered.
- I understand the information within this informed consent form.
- The participant does not give up any legal rights by signing this consent form.
- I agree for the participant to voluntarily participate in this research and give my consent on their behalf freely.
- I understand that the project will be conducted in accordance with the Informed Consent Form, a copy of which I have retained for my records.
- I understand the participant can withdraw from the project at any time, without penalty, and do not have to give any reason for withdrawal.
- I allow access to the participant's medical records and related personal health information as explained in this consent form.
- I understand that the participant's inpatient treatment team will be informed of study participation.

I consent the participant to:

- Complete an assessment of day-to-day functioning
- Participate in 4 weeks of cognitive adaptation training
- At the end of the 4 weeks, complete another assessment about their day-to-day functioning
- Following the second assessment, allow 2 months of unit staff follow-up on the learned skills from the intervention.
- At the end of the 2 months of unit staff follow-up, complete another assessment about their day-to-day functioning
- Following the third assessment, attend 1 focus group or individual feedback session (about 30 minutes in length) on their unit at CAMH that may be audiotaped with their permission.
    - Please select if we have your permission to audio record the participant's responses during the individual feedback session (check ONE box):
        - ☐ You have my permission to audio record the participant's responses during the individual feedback session
        - ☐ You *do not* have my permission to audio record the participant's responses during the individual feedback session.
            - Please select if you would like an individual interview to provide feedback that is *not* audio recorded instead (check ONE box):

- ☐ I would prefer an individual interview for the participant.
- ☐ I would *not* prefer an individual interview and, therefore, the participant will not participate in providing feedback.

- Please note that you are welcome to change your mind the day of the individual feedback session by notifying a member of the research team.

__

_____	_____	_____
Signature of Substitute Decision Maker	PRINTED NAME	Date

If signed by Substitute Decision Maker _____
PARTICIPANT NAME

_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

The following attestation must be provided if the participant or SDM is unable to read or requires an oral translation:

If the participant or SDM is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

_____	_____	_____
PRINT NAME of Interpreter	Signature	Date

_____
Language

☐ The consent form was read to the participant or SDM. The person signing below attests that the study as set out in this form was accurately explained to the participant or SDM, and any questions have been answered._____ __

_____	_____	
PRINT NAME of witness	Signature	Date

_____
Relationship to Participant

INFORMED CONSENT FORM- Provider

Study Title: A Study of Cognitive Adaptation Training in Inpatient Forensic Environments

Responsible Investigators: Sean Kidd 416-535-8501 ext. 6295, Centre for Addiction and Mental Health (CAMH); Courtney Brennan, CAMH; John Spavor, CAMH; Stephanie Penney, CAMH; Riley Saikaly, University of Toronto; Kerri Adams, University of Toronto.

INTRODUCTION

You are being invited to participate in a study to help the research team better understand your perspectives on the implementation of Cognitive Adaptation Training (finCAT) on your unit. You are invited to participate in this study because of your involvement in the finCAT intervention on your unit. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. You are free to answer or not answer any specific questions during the session.

WHY IS THIS RESEARCH BEING DONE?

The purpose of the study is to understand health care provider attitudes and perspectives about the implementation of Cognitive Adaptation Training on forensic inpatient units. We are interested in attitudes toward finCAT, perceptions of the impact of finCAT on clients' goals, and perceptions of team tension or conflict arising from the use of the intervention.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Each unit will have 1-2 unit champions, and primary nurses for the 6 involved clients will be invited to participate. Each focus group will have 6 to 10 participants.

WHAT ARE THE STUDY PROCEDURES?

This study will involve the completion of pre and post measures regarding clients involved in the study, your perspectives on the cognitive adaptation training intervention, and your participation in a focus group. A focus group is a small group of representative other clinicians who are asked to speak about their opinions as part of the research. A moderator and a note-taker (student investigators) will organize the focus group. Each focus group discussion will be one session lasting approximately 30 minutes and will take place on your unit at CAMH. You will be asked to speak about your experiences with the intervention. The focus group sessions may be audiotaped with your permission.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this focus group, you will be expected to:

- Share your perspectives on the implementation of finCAT
- Treat others in the session with respect

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

We do not anticipate there being any physical discomfort related to you participating in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

While there are no anticipated direct benefits to the participants, some participants may experience satisfaction from sharing their experiences to support our study objectives.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

All information that identifies you will be kept confidential and stored and locked in a secure location at the Centre for Addiction and Mental Health, that only the study personnel will have access to. In addition, electronic files will be stored on a secure hospital or institutional network and will be password protected. The investigators will dispose of your paper and computer-based records after the research obligations for the study have been met. Confidentiality will be respected and no information that discloses your identity will be released or published without consent unless required by law.

As part of the Research Services Quality Assurance role, this study may be monitored and/or audited by the Quality Assurance Team. Your research records may be reviewed during which confidentiality will be maintained as per CAMH policies and to the extent permitted by law.

As a part of a continuing review of the research, your study records may be assessed on behalf of the Research Ethics Board. A person from the research ethics team may contact you (if your contact information is available) to ask you questions about the research study and your consent to participate. The person assessing your file or contacting you must maintain their confidentiality to the extent permitted by law.

WHAT HAPPENS TO STUDY RESULTS?

After the data from the study has been analyzed, a report will be submitted to an academic journal. The data that you provide in the focus group will be anonymized (all identifiers removed like name, age, gender). This protects your privacy and also helps ensure that readers are fully informed about the trustworthiness of the research that has been done.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please let the research staff know. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

You will be given a copy of this signed and dated consent form prior to participating in this study. If you have questions about the study that are not answered in these Information Sheets, please ask them. In addition, if you have questions in the future you may contact the study investigators at the telephone numbers given on the first page.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the doctor who is in charge of the study at this institution. That person is:

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- All of my questions have been answered.
- I understand the information within this informed consent form.
- I do not give up any legal rights by signing this consent form.
- I agree to voluntarily participate in this research and give my consent freely.
- I understand that the project will be conducted in accordance with the Informed Consent Form, a copy of which I have retained for my records.
- I understand I can withdraw from the project at any time, without penalty, and do not have to give any reason for withdrawal.

I consent to:

- Attend 1 focus group (about 30 minutes in length) on my unit at CAMH that may be audiotaped with my permission.
    - Please select if we have your permission to audio record your responses during the focus group session (check ONE box):
        - ☐ You have my permission to audio record my responses during the focus group
        - ☐ You *do not* have my permission to audio record my responses during the focus group.
            - Please select if you would like an individual interview to provide feedback that is *not* audio recorded instead (check ONE box):
                - ☐ I would prefer an individual interview
                - ☐ I would *not* prefer an individual interview and, therefore, will not participate in providing feedback.

Please note that you are welcome to change your mind the day of the focus group by notifying a member of the research team.

_____	_____	_____
Signature of Participant	PRINTED NAME	Date
_____	_____	_____
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date