Letter of Information and Consent for Public Safety Personnel

Project Title:	Examining the effectiveness of Equine Assisted Learning for trauma-exposed public safety personnel
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You are being invited to take part in a research study entitled, *Examining the effectiveness of Equine Assisted Learning for trauma-exposed public safety personnel.* This study is being conducted by McMaster University. Participation in this study is entirely voluntary. To help you decide whether you would like to take part in this research, you should be aware of what is involved and any potential risks and benefits. Please take your time to review this letter of information, and if anything needs clarification or if you have any questions, please discuss this with a member of our research team.

STUDY PURPOSE

The purpose of this study is to evaluate a possible treatment for improving symptoms associated with trauma among public safety personnel (PSP; e.g., police officers, fire fighters, paramedics, emergency dispatchers, correctional workers, healthcare workers). As you may know, experiencing a traumatic event can negatively affect various aspects of a person's life. Examples of traumatic events can include physical, sexual, and/or emotional abuse; involvement in an automobile accident; and working in a healthcare environment during the COVID-19 pandemic. Symptoms that can accompany or follow the experience of a traumatic event include feeling overwhelmed by memories of the event, trying to avoid reminders the event, feeling overly alert to danger, and having difficulty regulating emotions. We also know that individuals who have experienced a traumatic event often experience certain cognitive (i.e., thinking-based) challenges, including problems with memory, focus, and planning, and that these

challenges can greatly interfere with everyday life. Unfortunately, there is little research on possible treatments for trauma, but we are hoping this study will be a helpful contribution. The treatment we are investigating through this study is called Equine Assisted Learning (EAL).

OVERVIEW OF EAL

EAL is an intervention through which interaction with a horse, guided by a certified EAL facilitator, creates the conditions for self-evaluation and personal growth. The EAL intervention associated with this study will be delivered at Cartier Farms in Spruce Home, Saskatchewan. Cartier Farms uses unmounted (ground-based) equine activities. This means there is no horseback riding involved in the program. The intervention involves 16 sessions delivered over 8 weeks by certified EAL facilitators. Each session focuses on a specific learning objective and involves a description of the day's exercises, the completion of an unmounted activity with a horse, a group debriefing about how the activity went, and an optional individual journal reflection.

The Cartier Farms lead facilitator, Gayle Cartier, and program director, Janice Boucher, will oversee EAL facilitation to ensure the intervention is delivered according to standard. To ensure the safety of all study participants, a mental health professional will be present at all sessions and all EAL facilitators have received a course in trauma-informed care.

While EAL will be facilitated by Cartier Farms, the data collection and analyses for this study will be conducted by researchers at McMaster University. As a result, you will interact with both EAL facilitators/clinicians at Cartier Farms and members of the McMaster University research team. If you participate in this study, the staff at Cartier Farms will be aware of your participation and that you have experienced a traumatic event, but they will not be aware of the details of the event(s) you have experienced.

ELIGIBILITY TO PARTICIPATE

You are eligible to participate in this study if you meet the following criteria:

- You are between the ages of 18 and 65 years;
- You speak English and are able to write your own name;
- You are currently or have previously been employed as a police officer, fire fighter, paramedic, healthcare worker, correctional worker, and/or emergency dispatcher;
- You have experienced at least one traumatic event related to your work as a public safety personnel (please note that a formal diagnosis of PTSD is not required to participate in this study);
- You are willing and able to attend 1.5-hour sessions twice/week for 8 weeks at Cartier Farms in Spruce Home, Saskatchewan (near Prince Albert);
- You are willing to complete pre-, post-, and follow-up treatment assessments and an in-depth interview about your experiences in the EAL program.

- You are willing to adhere to public health measures as per McMaster University policy at the time of the study;

- You have access to a smart-phone, computer, or tablet with a working microphone and camera; and

- You have access to consistent and reliable Internet connection.

There are some additional criteria you will need to meet in order to participate in this study. The research team at McMaster University will evaluate your eligibility to participate in this research study at your first research appointment.

WHAT IS INVOLVED?

We hope to enroll 80 participants as part of this study. These participants will be randomly assigned (i.e., by chance, like the flip of a coin) to one of two research conditions: (1) an EAL treatment condition, or (2) a "waitlist" condition (i.e., delayed treatment). Those assigned to the EAL treatment condition will be enrolled in EAL for 8 weeks, while those assigned to the waitlist condition will have EAL treatment delayed for approximately 6-7 months. After the waitlist participants have completed all research assessments (as described below), they will also be offered the opportunity to receive EAL treatment. By comparing the results from our two research conditions, we will learn whether EAL acts as an effective treatment for reducing symptom severity, cognitive impairments, and functional issues often associated with trauma. Full study participation includes completing a number of assessments which will help us track changes in trauma symptom severity, cognitive function, and other mental health concerns before and after EAL treatment. These assessments are described below. All EAL sessions will be completed at Cartier Farms. All research assessments will be conducted online using encrypted video and survey platforms with a McMaster University research team member.

There is a continuing need to protect participants from COVID-19 infection at this time and McMaster University COVID-19 protocols must be followed during this study. To be eligible to participate, you must be willing to comply with any public health measures in place at Cartier Farms and McMaster University at the time of your participation in the program. We will ask for your willingness to adhere to public health guidelines as part of the eligibility screening for the study.

Study Conditions

As noted above, all participants will be randomly assigned to one of two conditions: an EAL treatment condition or a waitlist condition. Details on what will happen in each condition are provided below:

i) EAL Condition: If assigned to be a participant in the EAL treatment condition, you will have two sessions of EAL per week for 8 weeks at Cartier Farms. Sessions will be 1.5 hours long. Each session will include a brief introduction to the session and objectives, followed by an exercise to be completed with the horse and a debriefing of the exercise. Journaling will be encouraged between sessions to reinforce learning. In addition to taking part in EAL, you will be

asked to complete research assessments at three time points: at the start of the study, 8-10 weeks later (once you have completed EAL), and then again 3 months later.

ii) Waitlist Condition: Participants in the waitlist condition will not receive EAL for approximately 6-7 months. They will also be asked to complete the assessments at the same time points as those in the EAL condition (at the start of the study, 8-10 weeks later (once the EAL condition has completed EAL), and then again 3 months later). After the 3-month follow-up assessments are completed, participants in the waitlist condition will be offered the opportunity to complete the 8-week EAL program at the next available time that it is offered.

Screening and Assessments

Each assessment time point will have 3 parts: i) a psychological interview and evaluation of trauma symptom severity, ii) self-completed "homework" evaluations of mental health and cognition, and iii) collection of biological indicators. If you are assigned to the EAL treatment condition, you will also be asked to complete an additional one-time, in-depth individual interview about your experience in EAL. Details about each of these components are provided below:

i) The psychological interview is expected to take approximately 2 hours per time point and will be completed via "Zoom for Healthcare," a secure videoconferencing platform that complies with the McMaster University's strict privacy requirements for healthcare services. The interview will include questions about your mood, traumatic experiences/symptoms, physical health, substance use, and other aspects of your life. This interview will initially help us determine whether you are eligible to participate in the study and, later, recognize any changes in your mental health over the course of the study. Please note that the results of the initial interview may indicate you are not eligible to complete the rest of the study. If this occurs, you will be compensated for your time with a $25 gift card and the data from your interview will be destroyed.

ii) The online homework questionnaires will take approximately 2 hours per time point to complete, and will cover topics like mental health symptoms, substance use, cognitive issues, and work functioning. These will help us recognize and understand any changes in your daily function. The questionnaires will be completed online using REDCap, a secure web-based survey platform. Questionnaire links will be emailed to you. You do not have to complete all the questionnaires in one sitting.

iii) The biological indicators will include ongoing measurement of your heart rate and sleep quality using a Garmin smart watch. You will be provided with this watch and asked to wear it for the duration of the study. You will have the option to pick up the Garmin watch at Cartier Farms or have it mailed to you.

iv) The in-depth individual interview will only be conducted with participants assigned to the EAL intervention group. The purpose of this interview is to help us understand your experiences in EAL and its impact on your trauma symptoms and other areas of your life. We will ask you about your experiences in the EAL program and whether/how the program

impacted you. The interview will take approximately 60-90 minutes and will be completed via Zoom for Healthcare with a member of the research team. With your permission, the interview will be audio-recorded and a transcript (i.e., written copy of the interview) will be created by a professional transcriptionist.

v) Attendance at EAL sessions: For those in the EAL condition, a staff member at Cartier Farms will take your attendance at each session – this will include whether you did or did not attend each session, and whether you were late, left early, or had an extended break during a given session. Attendance will not be taken for those in the waitlist condition. The attendance record will help us with our analysis of data by giving us information about how well you engaged with the EAL program. Your attendance will not impact your enrollment in the study; even if you do not attend, are late, leave early, or take an extended break during one or more sessions, you can still participate in the rest of the study. Your participation in this study – including individual sessions – is completely voluntary and you can choose not to attend or leave any session for any reason without consequence. If you will not be attending a session, expect to be late, or expect to leave early for one or more sessions, please let a staff member at Cartier Farms know. If you would like to withdraw from the study, you can email us at ealteam@mcmaster.ca.

Assessment Timeline

- The first two parts of the assessment (i.e., psychological interview, homework questionnaires) will take place at 3 different time points during the study:

    1. At the start of the study (i.e., before the EAL condition begins EAL),
    2. 8-10 weeks later (i.e., after the EAL condition finishes EAL)
    3. 3 months later (i.e., 3 months after the EAL condition finishes EAL).

    These assessments will be completed on separate days, not all on the same day.

- The biological indicators will be collected consistently over the entire course of the study using a Garmin smart watch.

- The in-depth individual interview will take place within 3 months the EAL condition completing EAL.

We recognize that this may seem like a lot of assessments, but the treatment may impact a broad range of factors, so we are trying to track some of the most relevant ones. Please know that we always try to pace assessments so you are as comfortable as possible. Breaks will be encouraged, as needed.

RISKS AND DISCOMFORTS

Assessments and EAL

Participants may become uncomfortable or emotionally upset during the assessments and/or during EAL when recalling negative memories/feelings. With this in mind, we make every effort to pace both the assessments and treatment as comfortably as possible. Research team members and/or Cartier Farms EAL facilitators will be available to help you regulate your emotions. Should you reveal suicidal intent at any point during your study participation, we will attempt to ensure your safety by reviewing resources and strategies with you, and if necessary, direct you to seek medical attention. Please note that EAL is not expected to increase these types of thoughts. If our assessment identifies a probable diagnosis of PTSD or another condition, if you would like, the principal investigator (or someone she delegates) can communicate this to your family doctor so that they can follow up with standard treatment. This treatment would not impact your enrollment in this study.

Use of Online Platforms

As with any online study, there is a risk that technological difficulties may interrupt your ability to participate in the online assessments. We will do our best to reduce this risk by providing you with resources, practice and guidance, and some flexibility in scheduling. Further, just like with online shopping, online technology has certain privacy and security risks. Despite the precautions taken and the secure platforms we have chosen, it is possible that information could be intercepted by unauthorized people (i.e., "hacked") or otherwise shared by accident. Although we attempt to reduce the consequences of this possibility by using secure services and study ID codes rather than participant names for the online activities, this risk cannot be completely eliminated. We will use Zoom for Healthcare for the interviews; you can find more information about this platform in the "Confidentiality" section of this form. We will use REDcap for online questionnaires; you can find information on their privacy and confidentiality policy here: https://projectredcap.org/software/mobile-app/privacypolicy/.

BENEFITS

Participants in this study may experience a reduction in cognitive difficulties, improvements in day-to-day functioning (e.g., social or work functioning), and/or a reduction in trauma symptoms, but these benefits cannot be guaranteed. Your involvement will help provide the scientific community with a better understanding of the emotional and cognitive challenges associated with trauma and contribute to the development of better treatments. As a participant, you may notice an increased awareness and understanding of your own psychological symptoms, but again, this cannot be guaranteed. We truly appreciate your participation.

RIGHT TO WITHDRAW FROM THE STUDY

As noted, participation in this study is voluntary. You may refuse to participate, refuse to answer any question, or withdraw from the study with no consequence. Withdrawal of your research data is possible until we begin analyzing the data, at which point results will have been pooled and impossible to separate. You do not waive any legal rights by completing the consent form associated with this study. If you are participating in another study, please inform our research team to ensure that there is no problem with participating in both. To withdraw from this study, please contact Dr. Margaret McKinnon at 905-522-1155 ext. 36645. Alternatively, you can email the study team at ealteam@mcmaster.ca or call at 647-551-2701.

CONFIDENTIALITY

We take the protection of your private information very seriously. All information collected from you for this study will be securely stored for 5 years. To help maintain confidentiality, all of your study-related material will be labelled with a study ID code (rather than your name) with the exception of the consent form, on which you will be asked to provide your name and email so we can send study-related materials to you electronically (e.g., links to questionnaires). Your study ID code will *not* appear on this consent form. This information will be securely stored on a server that is owned and maintained by McMaster University and where the principal investigator, Dr. McKinnon, is the Associate Chair of Research; no McMaster University staff outside the study team will have access to this data. A document linking your full name to your study code will be kept on our research coordinator's virus-, firewall-, and password-protected work computer, accessible only to them. We also want you to know that, due to the COVID-19 pandemic, members of our research team will often be working from home, which will include conducting the assessments from their homes. All online activities will be completed using password-, virus-, and firewall-protected work computers, and conducted using a secure Internet connection in private areas of our homes. Interview transcription will be done by a professional transcriptionist who has signed a confidentiality agreement and any identifying information (e.g., names of people or places) will be redacted from the transcript. All audio and text files will be password-protected and encrypted. Any paper questionnaires completed during assessments will be labelled with your study ID code only and locked in a private cabinet in our homes until it can be transferred to its final, secure destination at St. Joseph's Healthcare Hamilton, where the Principal Investigator's office is located[1]. At that time, paper files will be transported in a closed, unmarked container, kept in our possession at all times, and taken directly to our secure storage.

Your number-coded information will be shared with certain members of their research team located at McMaster University. Members of the research team from University of Regina and University of Saskatchewan will act as research consultants throughout the project but will not have a role in data collection or analysis and will not have access to study data. Consultants from Cartier Farms and EAL facilitators will be aware that you are participating in this study and that you have experienced trauma as part of your job, but will not have access to your data and will not be involved in data analyses.

As noted previously, pre-, post-, and follow-up testing data as well as information collected during the in-depth interviews will be stored on secure servers at McMaster University. Interview data will be transferred to a transcriptionist. The platform we will use to share these data is Microsoft SharePoint. All members of the research team must have an account requiring two-factor authentication to access the data and all individual files will be password protected and encrypted. You can find Microsoft's privacy and confidentiality policy here: https://privacy.microsoft.com/en-ca/privacystatement. We will combine the results of the pre-, post-, and follow-up data collection; the biological indicators; and the in-depth individual interviews for the purposes of scientific publication.

Throughout the study your personal information will be held in the strictest of confidence, but there are some circumstances in which we are legally obligated to release information, with or without your

1 Please note that this study is being conducted under the auspices of McMaster University. St. Joseph's Healthcare Hamilton has no involvement in this study other than being the site of any physical data storage.

consent. Such circumstances include any suspicion that a child is being abused, if we believe you are in imminent danger of hurting yourself or another person, if our files are subpoenaed by a court or judge, or if a healthcare professional has abused you or someone else and we know their name. In these situations, we are legally obligated to share information with the proper authorities to keep everyone safe.

While our research team is bound by strict privacy regulations, other participants in the EAL treatment groups will not have this same legal obligation. The need for privacy and confidentiality will be emphasized at the beginning of treatment, and we are hopeful that group members will respect one another's privacy by not repeating any information shared in sessions; however, this cannot be guaranteed. Also, as with any other group treatment, members will know one another's first name, unless participants choose to use a false name. Participants are advised to keep this mind when sharing personal information during EAL sessions.

As mentioned, all paper documents containing data (printed transcripts), ultimately, will be stored in locked cabinets in a locked office (B352) at St. Joseph's Healthcare Hamilton West 5th campus, with only certain members of the research team having access. Information from online questionnaires (via REDCap) will be kept on a secure network associated with Dr. McKinnon, at McMaster. Data will be stored for a maximum of 25 years. Members of our research team may also transfer this number-coded data to their firewall and password-protected work computers to conduct data analyses.

If the results of this study are published, your name will never be used, and no information that discloses your identity will be released or published. Representatives from Hamilton Integrated Research Ethics Board may audit this research study for quality assurance purposes. This would only be done to monitor the conduct of our research. These representatives are also bound to strict confidentiality rules.

Zoom for Healthcare Video-conferencing

Certain assessments will be conducted using a Zoom for Healthcare account that is compliant with Canada's data protection regulations, including the Personal Information and Electronic Documents Act (PIPEDA) and the Personal Health Information Protection Act (PHIPA). This is more secure than the personal Zoom accounts many people use at home, in part, because it prevents Zoom from recording user names and IP addresses. Zoom will not allow any monitoring, viewing, or tracking of video or audio content from group sessions, and it will not share customer data with third parties. No data about our Zoom for Healthcare account or meetings will be stored outside of Canada. All of our sessions will require a password to enter, and only study participants and will receive this password. Once begun, sessions will be locked, meaning no one else can join (or "Zoom-bomb").

PARTICIPATION IN FUTURE STUDIES

With your permission we would like to keep your contact information on file so that we can contact you for possible participation in future studies. This would not obligate you to participate in future studies, it would merely indicate that you would like the option of participating. You can indicate whether or not you grant this permission on the consent form at the end of this letter.

REIMBURSEMENT FOR PARTICIPATION

If you are deemed eligible to participate in the study, you will receive $50.00 in the form of an online gift card for each of the 3 assessment time points completed (i.e., psychological and online questionnaires at each of the 3 time points: pre/post/follow-up, for a maximum of $150). This is meant to reimburse you for your time and effort. As research funds are limited, we will not be able to compensate you for the individual EAL sessions, but we hope that study participation and any potential treatment effects will help make attendance worth your while. If you complete the initial psychological interview and are subsequently identified as being ineligible to participate, you will receive a $25 online gift card to compensate you for your time.

CONTACTS FOR PARTICIPANTS

If you have any questions or concerns about this study, please do not hesitate to contact us at ealteam@mcmaster.ca or 647-551-2701. Alternatively, you can contact the study investigators or research coordinator listed below. If you experience an mental health emergency, such as having suicidal thoughts, you are encouraged to contact the Mental Health and Crisis Support resources listed below or present yourself to the Emergency Department of your local hospital.

Mental Health and Crisis Support:

Saskatchewan province-wide professional health advice and mental health support

- Call 811 (available 24/7)
- https://sk.211.ca/emergency-crisis-hotlines/

Crisis Services Canada

- Call 1-833-456-4566 (available 24/7)

Other support services

- https://saskfirstrespondersmentalhealth.ca/need-help-now/

FURTHER QUESTIONS

If you have any questions or concerns, you may contact Dr. Margaret McKinnon at 519-824-1010 ext. 32252, or the research team at ealteam@mcmaster.ca or 647-551-2701.

HAMILTON INTEGRATED RESEARCH ETHICS BOARD

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HiREB). The HiREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, HiREB, at 905-521-2100 ext. 42013.

CONSENT FORM

Examining the effectiveness of Equine Assisted Learning for trauma-exposed public safety personnel

I have read and understood the letter of information and have had the nature of the study explained to me. All my questions have been answered to my satisfaction. I understand that I will receive a copy of the *Letter of Information* and *Consent*.

Do you consent to participate in this study?

[ ] Yes

[ ] No

If you answered "yes" to the question above, please provide the following:

Participant name: [open text]
Participant email: [open text]
Participant mailing address (if you want the Garmin watch to be mailed to you): [open text]

Do you consent to your contact information being kept on file so you may be contacted for future studies?

[ ] Yes

[ ] No

Do you consent to the use of your data for secondary analysis? This means that the research team could use your anonymized study data in the future to investigate other research questions. All regulations about confidentiality and privacy discussed in the form above will always apply to your data.

[ ] Yes

[ ] No