Date: July 3, 2014 at 1:53:42 PM PDT	Print	Close

The University of British Columbia
Office of Research Services
Clinical Research Ethics Board
Room 210, 828 West 10th Avenue
Vancouver, BC V5Z 1L8

H09-02860-006 **TAMER (Version 4.4)**

Principal Investigator: Karon E. MacLean

1. Principal Investigator & Study Team - Human Ethics Application [View Form]

1.1. Principal Investigator Please select the Principal Investigator (PI) for the study. Once you hit Select, you can enter the PI's name, or enter the first few letters of his or her name and hit Go. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.	Last Name MacLean	First Name Karon E.	Employer.Name Computer Science	Email maclean@cs.ubc.ca
Enter Principal Investigator Primary Department and also the primary location of the PI's Institution:				
1.2. Primary Contact Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.	Last Name MacLean	First Name Karon E.	Rank Professor	

1.3. Co-Investigators List all the Co-Investigators of the study. These members WILL have online access which will allow them to read, amend and track the application. These members will be listed on the certificate of approval (except BC Cancer Agency Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student's name in this section.

Last Name	First Name	Institution/Department	Rank
Garland	Elspeth	UBC/Medicine, Faculty of/Psychiatry/Child & Adolescent Psychiatry	Clinical Professor
Strang	Gordon Andrew	UBC/Science/Computer Science	Non-UBC Employee
Allen	Jeffrey	UBC/Science/Computer Science	Graduate Student
Cang	Xi Laura	UBC/Science/Computer Science	Undergraduate Student
Phan-Ba	Michael	UBC/Science/Computer Science	Graduate Student

1.4. Additional Study Team Members - Online Access List the additional study team members who WILL have online access to read, amend, and track the application but WILL NOT be listed on the certificate of approval.	Last Name	First Name	Institution/Department	Rank
1.5. Additional Study Team Members - No Online Access Click Add to list study team members who WILL NOT have online access to the application and will NOT be listed on the certificate of approval.	Last Name	First Name	Institution / Department	Rank / Job Title	Email Address
Tri Council Policy Statement2 (TCPS2) Tutorial All undergraduate and graduate students and					

medical residents are required to complete the TCPS2 Tutorial (CORE) before submission. This tutorial provides an essential orientation to Canadian human research ethics guidelines. The Principal Investigator and all Co-Investigators must be familiar with the TCPS2. Indicate completion of the TCPS2 (CORE) tutorial below: 1.6.A. All Undergraduate/Graduate Students:	Yes
1.6.B. All Medical Residents:	N/A (no medical residents participating in this study)
Comments:	
1.7. Project Title Enter the title of this research study as it will appear on the certificate. If applicable, include the protocol number in brackets at the end of the title. If this is a class-based project, see guidance on the right.	Touch-guided Anxiety Management via Engagement with a Robot Pet
1.8. Project Nickname Enter a nickname for this study. What would you like this study to be known as to the Principal Investigator and study team?	TAMER
2 Study Dates and Funding Information - Human Ethics Application [View Form]	
You plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date on the ethics certificate will reflect the approval date),	no
You plan to start data collection at a later date i.e., 2 months or more after approvals are obtained. Click the calendar icon below to select the dates (Internet Explorer) or enter the dates manually using the format yyyy-mm-dd. Estimated start date:	November 1, 2009
2.1. B. Estimated end date:	December 31, 2015
2.2.A. Types of Funds Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research. You must then complete section 2.3 and/or section 2.4 for the name of the source of the funds to be listed on the certificate of approval.	Grant
2.2.B. For Industry Sponsored studies, please provide a sponsor contact.	
2.2.C. Please enter any applicable information about your funding which is not already shown in Box 2.3 or 2.4 (including funding applied for but not yet received).	
2.3. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Services Please click Add to identify the research funding application/award associated with this study. Selecting Add will list the sources of all research funding applications that have been submitted by the PI (and the person completing this application if different from the PI). If the research funding	UBC Number / Title / Sponsor 08-1916 / HALO: Transparent guidance of networked interactions through a haptic-affect loop / Natural Sciences and Engineering Research Council of Canada (NSERC) 06-5400 / Robotic partnerships: multi-modal human robot interaction / Natural Sciences and Engineering Research Council of Canada (NSERC)

application/award associated with this study is not listed below, please enter those details in question 2.4.	
2.4. Research Funding Application/Award Associated with the Study not listed in question 2.3. Please click Add to enter the details for the research funding application/award associated with this study that is not listed in question 2.3. When you press Add you can do a search for your funding award by doing a search in the Sponsor box - over 7000 options are listed	UBC Number Title Sponsor
2.5.A. Is this a DHHS grant? (To view a list of DHHS funding agencies click on add in 2.5.B below)	no
2.5.B. If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant to box 9.8. of the application.	DHHS Sponsor List: Order: Active:
Attach DHHS Grant Application for each sponsor listed above	
2.6. Conflict of Interest Do any of the following statements apply to the Principal Investigator, Co-Investigators and/or their partners/immediate family members? Receive personal benefits in connection with this study over and above the direct cost of conducting this study. For example, being paid by the funder for consulting. (Reminder: receiving a finders fee for each participant enrolled is not allowed). Have a non-financial relationship with the sponsor (such as unpaid consultant, advisor, board member or other non-financial interest). Have direct financial involvement with the sponsor (source of funds) via ownership of stock, stock options, or membership on a Board. Hold patent rights or intellectual property rights linked in any way to this study or its sponsor (source of funds).	no
4. Study Type - Human Ethics Application [View Form]	
4.1. UBC Research Ethics Board Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:	UBC Clinical Research Ethics Board
N/A	
4.2.A. Institutions and Sites for Study	Institution: UBC; Children's and Women's Health Centre of BC (incl. Sunny Hill) Site: Vancouver (excludes UBC Hospital); BC Mental Health and Addictions Research Institute
	Experiments will be conducted either (a) in the researchers' labs on the UBC campus (ICICS Building); (b) at the Eaton Arrowsmith School, a private institution for children

4.2.B. Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., private physician's office, community centre, school, classroom, participant's home, in the field - provide details).	with mild to moderate learning disabilities, located on the UBC campus at: 204-6190 Agronomy Road University of British Columbia, Vancouver, BC V6T 1Z3 http://www.eatonarrowsmithschool.com/aboutus.html. (c) at BC Children's Hospital, located at: BCCH Mental Health Building P4, 4500 Oak Street,Vancouver V6H 3N1
4* Clinical Study Review Type [View Form]	
4.3. Relationship with other proposals 4.3.A. If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal.	H09-02536
4.3.B. If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.	We originally submitted this application to the BREB under the above number, i.e. prior to its initial CREB approval in December 2009. BREB requested us to copy and resubmit to CREB, then deactivate the original application.
4.3.C. Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details and attach any available relevant documentation in question 9.7.	no
4.4. Level of Risk After reviewing the minimal risk guidance notes and the criteria for minimal risk, does this study qualify for minimal risk review? Note that all studies which do not fall into the minimal risk category will undergo full board review.	yes
Peer Review If this research proposal has received any independent scientific/methodological peer review, please include the names of committees or individuals involved in the review. State whether the peer review process is ongoing or completed. All above minimal risk studies generally require a peer review. 4.5.A. External peer review details:	We have applied for funding for this project (CHRP, Notice of Intent level, 2010 competition; and BCIC NRAS, 2009 competition, 25% success rate). To date it has not been funded due to a lack of funds, but no methodological issues have been identified. Most components of the research methodology, including all aspects of the physiological sensing used here, have been peer-reviewed in past funded proposals by the PIs. These have been conducted by the grant agencies for each of the funding sources listed as well as for other sources administered by the PIs. In most cases, this has been NSERC; most recently, for the Strategic Grants Program. The single methodological aspect not covered in these *past* grants is the use of our physiological sensing techniques with children, rather than adults. This aspect was covered in the CHRP and NRAS grant proposals, whose reviews did not identify any concerns.
4.5.B. Internal (UBC or hospital) peer review details:	No internal peer review conducted.
4.5.C. If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place.	N/A
4.6. Harmonized review of multi-jurisdictional studies Please read and review the guidance	

note on the right prior to completing this question. Is this study a multi-jurisdictional study that will also require REB review/approval at one or more of the following institutions with which UBC has a collaborative review agreement? (See the guidance to the right for details about the harmonized process.) Simon Fraser University University of Alberta University of Northern British Columbia University of Saskatchewan University of Victoria (Note: If submitting an amendment for an already approved study, you must respond No to this question)	no
4.7.A Creation of a Registry (Data or Tissue Bank) Does this study involve the creation of a registry (data or tissue bank) for future use in other research? [if no, skip to 4.8]	no
4.7.B Is the purpose of this application exclusively to obtain approval for the creation of a research database, registry or tissue bank? [Note if the creation of the database or registry or tissue repository is part of a bigger project also included in this application, you must answer no below.]	no
Clinical Chart Review 4.8.A. Is this an application for research using the review of clinical charts?	no
4.8.B. Insert the date range of the charts to be included in this research.	
4.8.C. Is this a retrospective chart review where the only source of data will be medical charts/records that are currently in existence? (i.e., will pre-date the date of your ethics approval?)	
4.8.D. Is this a retrospective chart review study that will involve the collection of NO personally identifiable information of any sort?	
4.8.E. Is this a retrospective chart review study for which you are requesting a waiver of consent	
5. Summary of Study and Recruitment - Human Ethics Application for Clinical Study [View Form]	
5.1. Study Summary 5.1.A Provide a short summary of the project written in lay language suitable for non-scientific REB members. DO NOT exceed 100 words and do not cut and paste directly from the study protocol.	This project's goal is to advance a novel tool and technique to help young children attain independent anxiety regulation skills. Engagement will be utilized to give children access to cognitive training by interacting with an expressive animatronic pet. This robot will be programmed to respond physically to a combination of a child's pattern of touch and biometrically sensed emotional state in a way that rewards patience and progress.
	This research aims to replicate the therapeutic potential of human interactions with real animals in a nonthreatening, infinitely patient and non-allergenic personal robot that is programmed to respond physically to a combination of the child's pattern of touch and sensed anxiety. One focus is refining the ability of biometric sensing to detect emotional state and user engagement, specifically relating to anxiety and stress recognition in children. In our second focus, this technology will then be used to craft an engaging child-robot interaction such that the child is led towards and reinforced in

5.1.B Summarize the research proposal:	exercising mental control of his/her thoughts and feelings. Development will be an iterative, user-centered process that employs all members of the child's caregiving team. We have three primary child user bases (children, and their teacher/parent support teams). These are (1) a mildly affected population at the Eaton-Arrowsmith School (EAS) for children with learning disorders on the UBC campus, where many students have some degree of sub-clinical anxiety symptoms; (2) a significantly affected population from co-PI Garland's outpatient anxiety clinic at BC Children's Hospital, targeting children who have been clinically diagnosed with an anxiety disorder; and (3) a normal child population, recruited from e.g. UBC summer camps, local schools, and friends and family. In addition, we will perform initial pilot studies, whenever appropriate, on a fourth population (4) of more easily accessible adult populations with no known anxiety symptoms, recruited from the UBC Pt Grey community. The project goals are to discover the interactions and control flow that will engage the child and enable his/her mastery of physiological responses in difficult situations; and encode these physically and programmatically in a sensitive, expressive robot prototype. Following in-school or in-clinic evaluation and assessment, we plan to specify and build a version for independent in-home use. To date, several small evaluations have been conducted to examine different aspects of the research. The results support the effectiveness of the robotic pet's activity on physiological metrics linked to anxiety; the robotic pet's motions make changes to physiological response in the direction of relaxation. A total of 58 participants were involved in these experiments.
5.2. Inclusion Criteria Inclusion Criteria. Describe the participants being selected for this study, and list the criteria for their inclusion. For research involving human pluripotent stem cells, provide a detailed description of the stem cells being used in the research.	Participants must be able to understand the purposes of the experiment, and must be of sufficient cognitive development to be capable of giving and responding to verbal English feedback. Participants will be selected from four primary user groups. (1) Mildly affected child population: Participants from ages 7-17 will be recruited from the Eaton-Arrowsmith school upon recommendation of the EA school staff. These participants may have been identified as having mild anxiety or learning difficulties. (2) Significantly affected child population: Participants from ages 7-17 will be recruited from Garland's clinical practice at BC Children's Hospital. These participants have been identified as having a moderate degree of anxiety which would be managed primarily with anxiety self-regulation and coping skills. (3) Unaffected child population: Participants from ages 7-17 will be recruited from UBC summer camps, local schools, and friends and family. These child participants will be recruited as controls, based on their age; however an identification of mild anxiety or learning difficulties will not preclude participation in the study. (4) Unaffected adult population: adult participants must volunteer in response to a recruitment notice (see below); and must be 17-50 years of age. Participants 17 years and under, or those between the

	ages of 17 and 19 who are not attending University will require written parental consent. Adult participants will be recruited as controls, based on their age; however an identification of mild anxiety or learning difficulties will not preclude participation in the study. Distribution of subjects among these categories: Of the "n" subjects that are to be recruited to this study (7.2), we are targeting the following proportions: 30% (1) Mildly affected child population 30% (2) Significantly affected child population 20% (3) Unaffected child population 20% (4) Unaffected adult population. Of these, 40% will be controls (categories 3 and 4).
5.3. Exclusion Criteria Exclusion Criteria. Describe which potential participants will be excluded from participation, and list the criteria for their exclusion.	Participants who do not meet the above criteria will be excluded. In addition, clinically anxious children with severe anxiety disorders, or with concurrent disorders which would make the demands of the computer task or biofeedback process unsuitable (such as severe ADHD, or primary diagnosis of depression) will be excluded.
5.4. Recruitment Provide a detailed description of the method of recruitment. For example, describe who will contact prospective participants and by what means this will be done. Ensure that any letters of initial contact or other recruitment materials are attached to this submission on Page 9.	(1) Mildly affected child population: Children recruited from Eaton-Arrowsmith School will be contacted through recommendations of EA School faculty and staff, based on their suitability for the study. See attached parental information and consent form. (2) Significantly affected child population: Children recruited through the Anxiety Disorders Clinic at BC Children's Hospital will be contacted with an invitation letter and consent/assent forms shared with families identified by Garland and her colleagues as meeting inclusion criteria defined for this study.
5.5. Recruitment of Normal/Control Participants Describe how prospective normal/control participants will be identified, contacted, and recruited, if the method differs from the above.	(3) Unaffected child population: Children recruited from through UBC summer camp programs (such as "GEERing Up!" (http://www.geeringup.apsc.ubc.ca)) and local schools will be contacted via an invitation letter, consent and assent form which we will invite camp staff and teachers to distribute at their discretion and with permission of their program directors. Children recruited through friends and family of the research team will receive the same invitation letter and consent/assent forms directly from research team members. (4) Unaffected adult population: for adult participants, recruitment notices are posted in the ICICS building and throughout campus and/or posted to a voluntary subscription email list for UBC community members who wish to participate in experiments (HCI-experiments@cs.ubc.ca). See attached sample recruiting forms. The experimenter, typically a graduate student, will conduct follow-up communication.
5.6. Use of Records If existing records (e.g. health records, clinical lists or other records/databases) will be used to IDENTIFY potential participants, please describe how permission to access this information, and to collect and use this information will be	Existing records will not be used.

obtained.	
5.7. Summary of Procedures	Experiments will generally involve an interaction with either a robotic pet or calming visual and audio stimuli as a substitute while physiological responses are recorded through the use of biometric sensors. At times, the participant will also be invited to work on a primary task, chosen to be mildly challenging for that participant (see below). The robotic pet is a small, lap-sized device covered with hypoallergenic artificial fur. All interaction takes place by touching the robot's fur-covered body. At all times the creature's mechanisms remain covered by the creature's skin (artificial fur fabric) and a fiberglass shell. The mechanisms are not capable of acting in a way which could cause injury to the user. Active devices on the creature consist of a rear shell that is capable of moving slightly up and down, intended to simulate breathing, a purring mechanism which produces a gentle vibration and sound, a pulse mechanism that impacts the outside wall of the creature to create a gentle force and sound, and consumer-grade heating pads to generate a pleasant warmth. Passive devices consist of two rubber bulbs for the ears, whose hardness or softness is adjustable, and detected via squeezing the ears. Participants will generally be asked to keep the robot, which weighs about 3kg, on their laps during studies. Safety from any conceivable device malfunction is ensured through measures such as power-source limiting and insulation, low-force mechanical action, and avoidance of pinch points. Mechanisms will be driven either according to pre-programmed routines or in response to the user's physiological state, and the participant's physiological response recorded. The participant's physiological state will be assessed via physiological sensing using accepted non-invasive biometric techniques. Thought Technology Pro-Comp biometric sensors will be used. For typical interaction a blood volume pulse sensor will be attached via a strap to one finger of a participant, and a respiration sensor worn around the participant's abdomen. For more involved experiments ECG, EKG, skin conductance, and skin temperature sensors may also be worn. Sensors will be cleaned with alcohol swabs between trials, and for ECG and EKG disposable contact pads will be used. The primary task which the participant will at times be invited to work on is a computerized skill-testing task, for example one used at Eaton-Arrowsmith School in which the user answers questions about clock-reading at varying levels of difficulty. We will conduct a standardized anxiety test such as SCARED (see [2] in protocol) to learn each child's baseline emotional characteristics. We will also collect physiological response both as a baseline (no robot pet or computer task) and with both/either of the robot and computer task variations. Subjective data is collected through interviews or rating scales like graphical thermometer to triangulate objective performance-based data. Participants may be video recorded during data collection or interviewing.
6. Participant Information and Consent Process - Human Ethics Application for Clinical Study [View Form]	
6.1. Time to Participate How much time will a participant be asked to dedicate to the project beyond that needed for normal care?	The time commitment requested beyond normal care (for those participants receiving treatment for an anxiety disorder, typically members of group 2) will range from a single session of 1 (most common) to 3 hours; OR multiple (1 hour or less) sessions extending

	over 2 to 8 weeks. The greatest total amount of time (serially accumulated) anticipated in any experiment is 18-20 hours.
6.2. Time to Participate – Normal/Control Participants If applicable, how much time will a normal/control volunteer be asked to dedicate to the project?	See 6.1 for time commitment for any participant.
6.3. Risks/Harms Describe what is known about the risks (harms) of the proposed research.	There are no known medical or psychological risks associated with this research. All biometric sensors used have received FDA approval for medical uses. Participants can decline to wear the sensors or have them removed if they wish. Nothing will be done to inflict anxiety or stress on the participants. An experimental session is equivalent in risk to viewing a TV program, listening to a portable audio player or playing a non-violent, slow-action computer game.
6.4. Benefits Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.	Participants may be able to gain an increased ability to self-regulate their emotional state. Upon their request, participating families are kept updated about the results of the research However, participants may receive no benefit from participation in this study.
6.5. Reimbursement Describe any reimbursement for expenses (e.g. meals, parking, medications) or payments/incentives/gifts-in-kind (e.g. honoraria, gifts, prizes, credits) to be offered to the participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.	Adult participants are compensated at a rate of $10/hour, with bonuses for completing longer or multiple sessions. Snacks or lunch are provided where appropriate, e.g. for long sessions and/or focus groups spanning a lunchtime period. Child participants will be compensated with healthful edible treats or small toys.
6.6. Obtaining Consent Specify who will explain the consent form and consent participants. Include details of where the consent will be obtained and under what circumstances.	Discussion of informed consent will vary depending on the source population, as defined in Section 5.1: (1) Mildly effected child population, (3) unaffected child population and (4) unaffected adult population: The experimenter (a graduate or undergraduate student or postdoctoral student trained in ethical procedures for working with participants) will conduct all communication during recruitment for the experiment. (2) Significantly affected child population: Recruitment and explanation of consent/assent will be conducted by a clinically trained collaborator, e.g. Dr. Jane Garland or an appropriately specialized colleague working under her supervision. These participants will be recruited out of Garland's and her colleagues' anxiety clinic at BC Children's Hospital, via direct communication with eligible parents and children, offering them the invitation letter with attached consent. To prevent any sense of coercion or obligation based on the clinical setting, the family is asked to consider the request and if they are interested in pursuing the study, they can call back or mail the consent form to initiate the study involvement. In either case: when a potential participant responds to a recruitment notice, the experimenter explains the experiment and answers any questions. Informed consent (see attached forms) is obtained at the start of the experiment session, where the participant's right to withdraw without prejudice at any time is emphasized. If the potential participant is a minor, an information letter and consent/assent forms (attached in section 9.2) will be sent home with the student from school or clinic. Potential participants

	whose parents have given consent will not be asked to participate against their will.
6.7.A. Waiver/Alteration of Consent If you are asking for a waiver or an alteration of the requirement for participant informed consent, please justify the waiver or alteration and explain how the study meets all the criteria on the right. Please address each criterion on the right individually.	N/A
6.7.B. Waiver of Consent in Individual Medical Emergencies If you are asking for a waiver or an alteration of the requirement for participant informed consent in individual medical emergencies, please justify the waiver or alteration and explain how the study meets all the criteria on the right. Please address each criterion on the right individually.	
6.8. Time to Consent How long after being provided with detailed information/consent form about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given.	The participant will make a final decision about participation immediately after the consent form is read and explained. The participant will learn about the essential aspects of the experiment at the time of recruitment, which might be weeks or days prior to the experiment.
6.9. Capacity to Consent Will every participant have the capacity to give fully informed consent on his/her own behalf? Please click Select to complete the question and view further details.	Will the participant have the capacity to give fully informed consent? / Details of the nature of the incapacity / If not, who will consent on his/her behalf? / If not, will he/she be able to give assent to participate? / If Yes, explain how assent will be sought. No / Some participants will be between the ages of 7 and 19. / Parental consent will be obtained before experiments. / yes / An assent form will be given to children between the ages of 7-13. Subjects 14 and older would read the full consent and sign the assent statement at the end. All participants will be clearly informed that they may stop their participation during an experiment [Details]

	if they desire, and will not be made to participate against their will.
6.10. Renewal of Consent Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place.	N/A
6.11. Provisions for Consent What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the consent process (e.g. consent forms in Braille, or in languages other than English).	N/A
6.12. Restrictions on Disclosure Describe any restrictions regarding the disclosure of information to research participants (during or at the end of the study) that the sponsor has placed on investigators, including those related to the publication of results. Also, indicate any plans for communicating study results to participants.	None
7. Number of Participants and Drugs - Human Ethics Application For Clinical Study [View Form]	
7.1. Multi-Centre Studies 7.1.A. Is this a multi-centre study (involves centres outside of those applied for under this Approval?)	no
If known, please list the other sites below:	
7.1.B. Is this study being submitted for ethical approval to any other BC or Canadian Research Ethics Board?	Description: No
If yes, please provide the name of the REB(s) and if available, contact information:	
7.2. Number of Participants 7.2.A. How many participants (including controls) will be enrolled in the entire study? (i.e. the entire study, world-wide)	200
7.2.B. How many participants (including controls) will be enrolled at institutions covered by this Research Ethics Approval? (i.e. only at the institutions covered by this approval)	200
Of these, how many are controls?	40
7.3. Drug approvals Enter the generic name of any investigational drug(s) not yet approved or any marketed drug(s) used outside of its approved indication.	N/A
7.4. Marketed Drugs Enter the name of any marketed drug(s) used within its approved indication.	N/A
7.5. Natural Health Products Enter the name of any Natural Health Products used:	N/A

7.6. Experimental Drugs and Devices Enter the name of any new investigational devices, or marketed devices used in experimental mode, that will be used outside of their approved indication.	N/A
7.7. PERs Enter the name of any positron-emitting radiopharmaceuticals (PERs).	N/A
7.8. Health Canada Regulatory Approvals 7.8.A. Health Canada Regulatory Approvals Is this study a clinical trial or investigational test requiring Health Canada regulatory approval (If this study does not require Health Canada approval, skip to 7.10)	no
7.8.B. If Yes, check all that apply from the list below.	Description Regulatory Approval:
7.8.C. Name the sponsor/institution/investigator responsible for filing a Clinical Trial Application (CTA) or Investigational Testing Authorization (ITA) with Health Canada or Other.	
7.9. Details of Health Canada Regulatory Approvals If regulatory approval from a Health Canada directorate is required for this study, your certificate of ethical approval will not be released until the regulatory approval certificate, approval date and control number are received by REB administration. Click Add to enter the name of the regulatory agency, the date of the application (if pending) or the date of the approval, and the control number and the date of approval, for either the initial application or subsequent amendments. A copy of the approval (NOL, ITA, NOA) must also be attached in question 9.1.	Name of Agency Date of Approval Date of Pending Application:
Health Canada NOL Control Number	Health Canada NOL Control Number Date of Approval
7.10. Stem Cell Research Does this research fall within the categories of pluripotent stem cell research that need to be submitted to the CIHR Stem Cell Oversight Committee (SCOC)?	no
7.11. Registration for Publication of Clinical Trials 7.11.A. Does this clinical study fall within the definition stated on the right (in the guidelines)?	yes
7.11.B. If Yes, click Add to enter the following information. (Please note that registration by UBC ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available.)	Has it been registered? Indicate the Authorized Registry used: Enter your Clinical Trial unique identifier: no
7.12. US Regulatory Requirements 7.12.A. Is there a requirement for this research to comply with United States regulations for research ethics?	no
7.12.B. If yes, please indicate whether or not FDA (Investigational New Drug) number (drug	

studies) or an FDA Investigational Device Exception (IDE) is required for the research and provide documentation from the Sponsor or the FDA verifying the IND/IDE number, or explaining the study exemption status, in Question 9.1.C.	
8. Data Monitoring- Human Ethics Application For Clinical Study [View Form]	
8.1. Unblinding in an Emergency Describe the provisions made to break the code of a double-blind study in an emergency situation, and indicate who has the code.	N/A (No double-blind studies will be conducted).
8.2. Data Monitoring Procedures Describe data monitoring procedures while research is ongoing. Include details of planned interim analyses, Data and Safety Monitoring Board, or other monitoring systems.	All interventions on children with learning disabilities will be conducted in collaboration with appropriately trained staff (Eaton-Arrowsmith for mildly affected population, or BC Children's for the significantly affected population) who are responsible for the children's care. These staff are already monitoring the children being studied, and will be in regular communication with experiment staff regarding any observed, relevant changes in the children's behavior. In addition, our own experimental data will be analyzed and monitored as it is collected.
8.3. Study Stoppage Describe the circumstances under which the study could be stopped early. Should this occur, describe what provisions would be put in place to ensure that the participants are fully informed of the reasons for stopping the study.	Should the staff referred to in 8.2, or other medical personnel involved in the care of our (mildly or significantly) learning-disabled subjects, discover and express concerns that can be attributed to our experimental interventions, the study will be paused until these concerns are fully addressed. If they cannot be addressed, the study will be halted. (However, we believe that the likelihood of this happening is extremely low, given the low-risk nature of the intervention).
8.4. Personal Identifiers 8.4.A. Describe how the identity of the participants will be protected both during and after the research study, including how the participants will be identified on data collection forms.	During study: because of personal nature of experimenter-subject interaction, it will not be practical to completely anonymize data collection records. We will refer to subjects by initial and code. After research study and in all publicized references, subjects will be referred to with full anonymity. Images (still and video) will be used only by explicit permission, with identifying regions (e.g. face) obscured.
8.4.B. Will any personal health information or personal identifiers be collected?	no
If yes, please describe what personal identifying information will be collected, and justify the need for it to be collected.	
8.5. Data Access and Storage 8.5.A. Explain who will have access to the data at each stage of processing and analysis, and indicate whether a current list of the names of study personnel (including co-investigators) and their delegated tasks will be maintained in the study file. If a list will not be maintained, please explain.	Secured records are accessible only to the principal investigator and the laboratory staff (graduate student, postdoc) involved in the specific study, as listed in Section 1 of this form. A list of study personnel allowed such access will be maintained in the study file as requested.
8.5.B. Describe how the data will be stored (e.g., computerized files, hard copy, video-recording, audio recording, personal electronic device, other).	No individual identification is permanently kept or published. The raw data (which generally does not include information of a potentially sensitive nature to participants) are stored on UBC Computer Science or Mechanical Engineering secure servers and locked through password protection. These include sensor data and video or audio recordings collected (by permission) in the lab or students' school environment, performance on primary task during data collection, and observational notes.

8.5.C. Describe the safeguards in place to protect the confidentiality and security of the data.	- stored only on secured UBC servers as indicated above - password protected and accessible only by authorized experiment staff - The names of participants are removed from the data files after relevant demographic data have been coded (age, sex, handedness, etc).
8.5.D. If any data or images are to be kept on the Web, what precautions have you taken to prevent it from being copied?	No information will be kept on web, outside of non-confidential published results and images.
8.6. Disposition of Study Data 8.6.A. Describe what will happen to the data at the end of the study (including how long the study data will be retained, when and how the data will be destroyed), and what plans there are for future use of the data, including who will have access to the data in the future and for that purpose. If this study involves the creation of a research database or registry for the purpose of future research, please refer to the Guidance note linked on the right and provide the requisite information.	The data are stored for an indefinite period in anonymized form. Data will be stored for at least 5 years after used in any published or presented work. There are not presently plans for future use of the data beyond the purpose of this study.
8.6.B. If applicable, describe what will happen to the study samples at the end of the study, including how long the study samples will be retained and where, when and how the samples will be destroyed, and what plans there are for future use of the samples, including who will have access to the data in the future and for what purpose.	
8.7. Data Transfer to Other Institutions Will data be sent outside of the Institution where it is being collected?:	no
If yes, please describe the type of data to be transferred, who the data will be transferred to, where the data will transferred, and how the data will be sent.	
8.8. Data Transfer to Institution Will the researchers be receiving data from other sites?:	no
If yes, please describe the type of data that will be received, who it will be received from, where it will be received from, and how the data will be received.	
8.9. Data Linkage 8.9.A. Will the data be linked to any other data source (including a biorepository)?	no
8.9.B. Identify the data set, how the linkage will occur, and explain how confidentiality regarding the shared information will be preserved.	

9. Documentation - Human Ethics Application for Clinical Study [View Form]

9.1.A. Protocol Examples of types of protocols are listed on the right. Click Add to enter the required information and attach the documents.	Document Name	Version	Date	Password (if applicable)
	TAMER protocol - changes highlighted	2.1	December 8, 2010	[View]

9.1.B. Health Canada regulatory approval (receipt will be acknowledged)	Document Name Version Date Password (if applicable)
9.1.C. FDA IND or IDE letters (receipt will be acknowledged)	Document Name Version Date Password (if applicable)
9.2. Consent Forms Examples of types of consent forms are listed on the right. Click Add to enter the required information and attach the forms.	Document Name Version Date Password (if applicable) Study Participant and Parent Consent Form - changes highlighted & footer revised 1.6 July 2, 2014 [View] Study Participant and Parent Consent Form - changes highlighted 1.4 December 8, 2010 [View]
9.3. Assent Forms Examples of types of assent forms are listed on the right. Click Add to enter the required information and attach the forms.	Document Name Version Date Password (if applicable) Study Participant Assent Form - changes highlighted 1.4 December 8, 2010 [View]
9.4. Investigator Brochures/Product Monographs Please click Add to enter the required information and attach the documents.	Document Name Version Date Password (if applicable)
9.5. Advertisement to Recruit Participants Examples are listed on the right. Click Add to enter the required information and attach the documents.	Document Name Version Date Password (if applicable) Study Invitation Letter - changes highlighted / footer revised 1.6 July 2, 2014 [View] Study invitation letter 1.3 June 25, 2010 [View]
9.6. Questionnaire, Questionnaire Cover Letter, Tests, Interview Scripts, etc. Please click Add to enter the required information and attach the documents.	Document Name Version Date Password (if applicable)
9.7. Letter of Initial Contact Please click Add to enter the required information and attach the forms.	Document Name Version Date Password (if applicable)
9.8. Other Documents 9.8.A. Other documents: Examples of other types of documents are listed on the right. Click Add to enter the required information and attach the documents.	Document Name Version Date Password (if applicable) SCARED anxiety assessment: pre-screen 1.0 June 28, 2010 [View] SCARED anxiety assessment: child questions 1.0 June 28, 2010 [View] SCARED anxiety assessment: parent questions 1.0 June 28, 2010 [View]
9.8.B. If a Web site is part of this study, enter the URL below. Since URL's may change over time or become non-existent, you must also attach a copy of the documentation contained on the web site to this section or provide an explanation.	
10. Fee for Service - Human Ethics Application for Clinical Study [View Form]	

Please indicate which of the following methods of payment will be used for this application.	N/A (Not funded by an Industry For-Profit Sponsors)
Enter information stating when the fee will be sent:	
11. UBC Children's and Women's Research Ethics Board [View Form]	
11.1. In order for a research project to be undertaken at C&W, either an employee or a member of the medical staff (as legally defined) needs to be designated as the Principal Investigator. This individual must have actual responsibility with respect to the project. Select the Principal Investigator for the Children's and Women's Health Centre if different from the Principal Investigator listed in question 1.1.	Last Name: Garland First Name: Elspeth Rank: Clinical Professor
11.2. Does the Children's and Women's Principal Investigator in question 1.1 (and 11.1, if different) have a UBC academic or clinical appointment?	yes
Select Browse to attach the declaration form.	
11.3. Select which hospital form(s) are required for this application.	Not Applicable
If you selected Other Resource/Service Utilization, please specify below.	
12. Save Application - Human Ethics Application [View Form]	

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