# *ETHICS REVIEW APPLICATION FORM FOR*

# *SUPERVISED AND SPONSORED RESEARCHERS*

(For use by graduate students, post-docs, residents, external investigators, and visiting professors/researchers)

**Before you start, familiarize yourself with:**

[**TCPS2**](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/)

[**Application instructions**](http://www.research.utoronto.ca/wp-content/uploads/documents/2015/02/Instructions-for-Ethics-Review-Application-Form-Version-March-2015.pdf)Office[**FAQs**](http://www.research.utoronto.ca/wp-content/uploads/documents/2015/02/FAQs-for-Site-March-20151.pdf)

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| **SECTION A – GENERAL INFORMATION** |

1. **TITLE OF RESEARCH PROJECT**

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| The Molecular Misconception Decision Tree: A Visualized Assessment |

**2. INVESTIGATOR INFORMATION**

**Investigator:**

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| Title (e.g., Dr., Ms., etc.): Ms.  | Name: Erina He |
| Department (or organization if not affiliated with U of T): University of Toronto |
| Mailing address: 13 Borden Street, Toronto ON M5S 2M8 |
| Phone: 6474701121  | Institutional e-mail: Erina.he@mail.utoronto.ca |

**Level of Project:**

|  |
| --- |
| Student Research: Doctoral [ ]  Masters [x]   |
| Post-Doctoral Research [ ]  Visiting professor/External researcher [ ]  Course Based [ ]   |
| CBR/CBPR [ ]  Other [ ]  (specify:      ) |

**Supervisor/Sponsor (must be a UofT faculty member with research privileges):**

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| Title: Dr.  | Name: Jodie Jenkinson |
| Department: : Biology (Biomedical Communications), UTM |
| Mailing address: HSC Rm 324, 3359 Mississauga Rd N., Mississauga, ON, L5L 1C6 |
| Phone: 905-569-4263  | Institutional e-mail: j.jenkinson@utoronto.ca |

**Co-Investigators:**

Are co-investigators involved? Yes [ ]  No [x]

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| Title:  | Name:  |
| Department (or organization if not affiliated with U of T):  |
| Mailing address:  |
| Phone:  | Institutional e-mail:  |

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| Title:        | Name:       |
| Department (or organization if not affiliated with U of T):       |
| Mailing address:       |
| Phone:        | Institutional e-mail:       |

 ***Please append additional pages with co-investigators’ names if necessary.***

1. **UNIVERSITY OF TORONTO RESEARCH ETHICS BOARD:**

Social Sciences, Humanities and Education [ ]  Health Sciences [x]  HIV/AIDS [ ]

To determine which Research Ethics Board (REB) your application should be submitted, please consult: <http://www.research.utoronto.ca/about/boards-and-committees/research-ethics-boards-reb/>

1. **LOCATION(S) WHERE THE RESEARCH WILL BE CONDUCTED:**

(a) If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a school), please include all administrative consent letters. It is the responsibility of the researcher to determine what other means of approval are required, and to obtain approval prior to starting the project.

University of Toronto [x]

Hospital [ ]  specify site(s)

School board or community agency [ ]  specify site(s)

Community within the GTA [ ]  specify site(s)

International [ ]  specify site(s)

Other [ ]  specify site(s)

(b) For all off-campus research, whether in the local community or internationally, the researcher should consult with the [Framework on Off-Campus Safety](http://www.cie.utoronto.ca/safety-abroad/Framework-on-Off-Campus-Safety.aspx), [Guidelines on Off-Campus Safety](http://www.cie.utoronto.ca/safety-abroad/Off-Campus-Safety-Guidelines.aspx), and [Guidelines on Safety in Field for institutional requirements](http://www.ehs.utoronto.ca/Assets/ehs%2BDigital%2BAssets/Guidelines%2Bon%2BSafety%2Bin%2BField%2BResearch.pdf).

(c) **The University of Toronto has an agreement with the Toronto Academic Health Sciences Network (TAHSN) hospitals regarding ethics review of hospital-based research where the University plays a peripheral role. Based on this agreement, certain hospital-based research may not require ethics review at the University of Toronto. If your research is based at a TAHSN hospital, please consult the following document to determine whether or not your research requires review at the University of Toronto.** <http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/humans-in-research/> - “Administrative review” heading toward the bottom of the page.

**5. OTHER RESEARCH ETHICS BOARD APPROVAL(S)**

(a) Does the research involve another institution or site? Yes [ ]  No [x]

(b) Has any other REB approved this project? Yes [ ]  No [x]

If **Yes**, please provide a copy of the approval letter upon submission of this application.

If **No**, will any other REB be asked for approval?

Yes [ ]        (please specify which REB) No [x]

**6. FUNDING OF THIS PROJECT**

(a)

|  |  |  |
| --- | --- | --- |
| Funding Status | Source and Type | Details |
| Funded [ ]  | Agency:       | Fund #: 4      (6 digits)  |
| Agency:       | Fund # :4      (6 digits) |
| Applied for funding [ ]  | Agency:       | Submission date:        |
| Agency:       | Submission date:       |
| Unfunded [x] If unfunded, please explain why no funding is needed: |

**7. CONTRACTS AND AGREEMENTS**

(a) Is this research to be carried out as a contract or under a research agreement?Yes [ ]  No [x]

If yes, is there a University of Toronto funding or non-funded agreement associated with the research? Yes [ ]  No [ ]

If **Yes,** please append a copy of the agreement with of this application.

Is there any aspect of the contract that could put any member of the research team in a potential conflict of interest? Yes [ ]  No [x]

 If yes, please elaborate under #10.

(b) Is this a Division 5, Health Canada regulated clinical trial that involves drugs, devices or natural health products?

Yes [ ]  No [x]  (if so, the application must be reviewed by the full board)

**8. PROJECT START AND END DATES**

Estimated start date for the component of this project that involves human participants or data: March 1, 2016

Estimated completion date of involvement of human participants or data for this project: July 15, 2016

**9. SCHOLARLY REVIEW:**

1. Please check one:

1. [x]  The research has undergone scholarly review by thesis committee, departmental review committee, peer review committee or some other equivalent (Specify review type – e.g., departmental research committee, supervisor, CIHR, SSHRC, OHTN, etc.):

1. [ ]  The research will undergo scholarly review prior to funding

(Specify review committee – e.g., departmental research committee, SSHRC, CIHR peer-review committee, etc.):

1. [ ]  The research will not undergo scholarly review (Please note that all research greater than minimal risk requires scholarly review)
2. If box I or II above was checked, please specify if:

[ ]  The review was/will be specific to this application

[ ]  The review was/will be part of a larger grant

**10. CONFLICTS OF INTEREST**

(a) Will the researcher(s), members of the research team, and/or their partners or immediate family members:

 (i) Receive any personal benefits (e.g., financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection with this study? Yes [ ]  No [x]

 (ii) If **Yes**, please provide further details and discuss how any real, potential or perceived conflicts of interest will be managed during the project. (Do not include conference and travel expense coverage, or other benefits which are considered standard for the conduct of research.)

N/A

(b) Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that have been placed on the investigator(s). These restrictions include controls placed by the sponsor, funding body, advisory or steering committee.

There is no restriction placed on the in access or disclosure of information on the investigator. However, information will be collected anonymously in the study.

(c) Where relevant, please explain any pre-existing relationship between the researcher(s) and the researched (e.g., instructor-student; manager-employee; clinician-patient; minister-congregant). Please pay special attention to relationships in which there may be a power differential – actual or perceived.

There is no pre-existing relationship between the investigators Erina He, Jodie Jenkinson, Gael McGill, Michael Corrin and the student participants to be researched. Furthermore, all data collected from the participants will be collected and analyzed anonymously thus should negate any future concern in this matter.

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| **SECTION B – SUMMARY OF THE PROPOSED RESEARCH** |

**11. RATIONALE**

Describe the purpose and scholarly rationale for the proposed project. State the hypotheses/research questions to be examined. The rationale for doing the study must be clear. Please include references in this section.

Undergraduate level of conceptual understanding at the molecular level are often superficial and punctured with fallacies when tested; however, in order to move forward, students must be able to grasp complex and abstract ideas at the fundamental levels. Current studies show that students in particular have trouble understanding the role of random movement in the molecules that take place in all biological processes (Chi 2005). However, identifying where the misconceptions stems from can be difficult due to current student testing methods.

Formative assessments are important in science education in that not only can we use them as a way to quantitate education progress of students, but they are often the only way we receive feedback to revise classroom instruction (Bell 2002.) The use of visual aids in the assessment is of interest due to the additional information that can be grasped intuitively through visualizations. Studies have been consistent on the effectiveness of information processing via the use of animation (McClean 2005, Mayer 2002.) 3D animation have shown to be more effective in explaining difficult biological processes at the molecular level than other traditional methods (Chang & Linn, 2013.) Animation facilitates the understanding of information by providing additional information that cannot be displayed from static images, which in turn helps the learner to build a stronger mental model (Ainsworth, 2008.)

The primary goal of this project is to create a visual assessment that allows educators to probe and study areas of weakness in a student’s understanding of molecular biology. To achieve this, topics to be covered in this study include: 1) movement of biological molecules under various conditions, 2) the mechanism of movement of biological molecules, and 3) movement of biological molecules of various sizes. We will be comparing metrics of our visual assessment with a plain-text assessment to gain insight on the usefulness on visualizations in a formative testing environment.

**12. METHODS**

(a) Please describe all formal and informal procedures to be used. Describe the data to be collected, where and how they will be obtained and how they will be analyzed.

**Materials:** An existing list of questions and answers for the assessment have been put together by Dr. Jenkinson’s team (**Appendix E**). I will be building on top of these existing questions and answers by adding a 3D animation to each of the answer choices to represent the statement with no discernable bias. Roughly 30 short 5s-10s animations will be created in Audodesk Maya, Molecular Maya, and Adobe AfterEffects.

**Participants and Measures:** Roughly 50-100 undergraduate biology students will be recruited for this study. Students will be recruited from one or more of these biology courses from the University of Toronto Mississauga campus during the 2016 summer session. Approximately half the student participants will be taking a control text-based assessment while the other half will be taking the exact same assessment with a visual component. Effectiveness of the visual assessment will be assessed by comparing its results to the text-based assessment.

**Procedure:** Students participants from the undergraduate course recruited via an in-class announcement and UofT portal announcement. Upon agreeing to participation, students will login to a web based survey where they will be randomly assorted into either the control text-based assessment group, or the visual assessment group. A short identical background questionnaire and multiple choice general science literacy survey will be given to the student prior to the assessment of the study. The pre-test will collect information on the student’s overall literacy in broad biology topics.

Students will be either taking a text-only assessment or an identical assessment with 3D animations in addition to multiple choice answers (**Appendix E**). The study group and the control group will not be notified the existence of both exams. The molecular assessment will vary in length depending on the student’s answer on each of the multiple choice questions, ie: certain questions will be skipped if the student picks a certain choice on the previous question. Students will be encouraged to complete the 20-30min assessment in one continuous sitting; however, they will be able to continue from where they have left off should they close or leave the page. Once an answer choice has been selected, students will not be able to change their answer. In addition to the answers for each multiple choice question, a measure of the student’s confidence for their answer choice will also be collected via a bar gauge varying from 0% (if the student has guessed) to 100% (student has complete confidence in their answer.) Upon completing the exam, an optional feedback form for the effectiveness of the survey will be given to the student for the group that received the visual assessment.

Data collected from the assessments will be stored online in a password protected MySQL database. Collected information will be associated with a random number-letter sequence generated by the server upon the student login to maintain anonymity of the participant.

**Analysis:** Both quantitate data and qualitative data will be analyzed in post-study. Pearson’s correlation analyses will be used for the comparison of score statistics between the control group (text-only answer choices) and the tested group (text + visual answer choices) to investigate if there is a relationship of student performance between the two assessments. Performance as a whole as well as performance at individual questions will be measured to investigate the effectiveness of using a visual aid in helping student better grasp the concept that is being tested. Other variable to be analyzed include student confidence between the two conditions, and time spent at viewing each animation before picking an answer choice. These metrics will be measured using the stand two-tailed t-test with significance established at P <.05. Qualitative data from post-assessment feed will be analyzed to measure the student’s perceived benefit or otherwise for the visual assessment.

(b) Attach a copy of all questionnaires, interview guides and/or any other instruments.

(c) Include a **list of appendices** here for all additional materials submitted (e.g., Appendix A – Informed Consent; Appendix B – Interview Guide, etc.):

A. Recruitment materials

B. Information and consent

C. General information questionnaire

D. General Science / Biology Literacy Survey

E. Molecular Biology survey question list

F. Feedback form

G. References

**13. PARTICIPANTS, DATA AND/OR BIOLOGICAL MATERIALS**

(a) Describe the participants to be recruited list the eligibility criteria, and indicate the estimated sample size (i.e. min-max # of participants). Where applicable, please also provide a rationale for your choice in sample size and/or sample size calculation.

Participants will be undergraduate biology students over the age of 18 enrolled in one of these summer courses BIO152, BIO206, or BIO153, BIO207 [Schedule of summer courses is currently not finalized, however based off previous years, we predict these courses will be offered. We have received provisional approval from Fiona Rall, the associate chair of biology teaching stream, for this study]. We estimate a sample size of 50-100 participants from previous similar studies. Participation is voluntary, however a small incentive for a .5% increase in the student’s overall grade will be given should they choose to participate. Information regarding the participants include age, science background, and biological literacy; this data along with the assessment data will be collected anonymously.

(b) Where the research involves extraction or collection of personally identifiable information, please describe the purpose, from whom the information will be obtained, what it will include, and how permission to access the data is being sought. (Strategies for recruitment are to be described in section #15.)

Participant data such as gender, age, and education level will be collected at the beginning as a short demographic survey. This information can be helpful in later analysis to establish any correlation with participant performance. However, this information will be associated with a randomly generated ID and will not contain anything identifiable feature back to the participant. Information will be encrypted and stored on a secure server and will not be released to other parties outside of this study.

(c) Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulties understanding informed consent, history of exploitation by researchers, power differential between the researcher and the potential participant)? If so, please provide further details below.

There is no group or individual-level vulnerability in this study.

(d) If your research involves the collection and/or use of biological materials (e.g. blood, saliva, urine, teeth, etc.), please provide details below. Be sure to indicate how the samples will be collected and by whom.

N/A

**14. EXPERIENCE OF INVESTIGATORS WITH THIS TYPE OF RESEARCH**

(a) Please provide a brief description of previous experience by (i) the principal investigator/supervisor or sponsor, (ii) the research team and (iii) the people who will have direct contact with the participants. If there has not been previous experience with this type of research, please describe how the principal investigator/research team will be prepared.

i) Dr. Jodie Jenkinson (PI) ) has extensive experience in human subjects research. This includes educational studies with post-secondary student populations (active protocol #28171) as well as research examining the needs of vulnerable patient groups. Professor Jenkinson teaches a graduate level course (MSC2008H) that addresses the design and evaluation of educational material for specific target audiences.

ii) The investigator Erina He is an MscBMC student with background in industry research and development. Although research with human projects has not been a large part of her background, she is familiar with scientific research methods.

**15. RECRUITMENT OF PARTICIPANTS**

Where there is recruitment, please describe how, by whom, and from where the participants will be recruited. Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g., living in a community, visiting on a bi-weekly basis, attending organized functions). If relevant, describe any translation of recruitment materials, how this will occur and whether or not those people responsible for recruitment will speak the language of the participants.

Students from one of the following undergraduate courses BIO152, BIO206, or BIO153, BIO207 will be recruited via an in-class announcement and Black Board notification. Recruitment announcements will be given one week before the survey is scheduled by Erina He. A reminder email will be sent out to enrolled students a day prior to the survey (**Appendix A.)**

**Attach a copy of all posters, advertisements, flyers, letters, e-mail text, or telephone scripts to be used for recruitment as appendices.**

**16. COMPENSATION

Please see U of T’s** [**Compensation and Reimbursement Guidelines**](http://www.research.utoronto.ca/wp-content/uploads/2010/01/Guidelines-for-Compensation-and-Reimbursement-of-Research-Participants-Approved-Feb-16-11.pdf)**.**

(a) Will participants receive compensation for participation?

 FinancialYes [ ]  No [x]

 In-kind Yes [ ]  No [x]

 Other Yes [x]  No [ ]

(b) If **Yes**, please provide details and justification for the amount or the value of the compensation offered.

A potential 0.5% increase in student marks will be offered as participatory incentive should course instructor approves. In order to receive the mark, students must complete the assessment in full. The small incentive should be enough to encourage voluntary participation, and also mitigate exam performance related anxiety should that be a concern for the study. Students will also be explicitly told that the award will be given for participation not how well they perform on the assessment.

(c) If **No**, please explain why compensation is not possible or appropriate.

 N/A

(d) Where there is a withdrawal clause in the research procedure, if participants choose to withdraw, how will compensation be affected?

Withdrawal clause will be stated in the consent form before the assessment. Should the participant choose to withdraw after he or she have completed the full assessment, they will still be rewarded the 1% for participation. However, if the student withdraws before they complete the assessment, the 1% will not be rewarded.

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| **SECTION C –DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH** |

**17. POSSIBLE RISKS**

(a) Please indicate all potential risks to participants as individuals or as members of a community that may arise from this research:

(i) Physical risks (e.g., any bodily contact or administration of any substance): Yes [ ]  No [x]

(ii) Psychological/emotional risks (e.g., feeling uncomfortable, embarrassed, or upset): Yes [x]  No [x]

(iii) Social risks (e.g., loss of status, privacy and/or reputation): Yes [ ]  No [x]

(iv) Legal risks (e.g., apprehension or arrest, subpoena): Yes [ ]  No [x]

(b) Please briefly describe each of the risks noted above and outline the steps that will be taken to manage and/or minimize them.

It is possible that some students may feel uncomfortable or anxious under testing environments. Participants will be explicitly told that their responses will have no negative impact on their grade and that a bonus 1% will be rewarded for solely on participation. They will also be reminded that participation is voluntary and that they are not pressured to be a part of the study. In the scenario that participants feel uncomfortable with sharing information on the demographic questionnaire, they will be reminded all answers will be collected anonymously and stored in a secured server and that further analysis of the collected data will be unassociated the student.

**18. POSSIBLE BENEFITS**

* Describe any potential direct benefits to participants from their involvement in the project
* Describe any potential direct benefits to the community (e.g., capacity building)
* Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

We hope that participants will have a broader understanding of the molecular environment by seeing it visualized in multiple versions. We intend to publish the findings of the study in a peer-reviewed article in hopes to show the merits of using visualizations in academic testing settings and encourage further studies of similar kind. In the long run, we hope that studies like ours will improve the design biological courses in undergraduate programs so that students will have less miscomprehensions about the molecular environment.

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| **SECTION D – INFORMED CONSENT**  |

**19. CONSENT PROCESS**
(a) Describe the process that will be used to obtain informed consent and explain how it will be recorded.  Please note that it is the quality of the consent, not the form that is important. The goal is to ensure that potential participants understand to what they are consenting.

Consent will be obtained via an online form prior to the start of the assessment, accessible through the UofT Blackboad portal. Students will consent using their UTORid and checking the “I, the participant, agree…. Etc” box. The consent form will inform the participant that any information that they provide to this study will be anonymized with no traceable identification back to them, and that performance on the study will not affect their grade in the course. They will also be made aware that may withdraw from the study at any given point and that doing such will result in no academic penalty **(Appendix B.)**

Upon agreeing to such terms, the students will be able to proceed to the study.

(b) If the research involves extraction or collection of personally identifiable information from or about a research participant, please describe how consent from the individuals or authorization from the data custodian (e.g., medical records department, district school board) will be obtained.

N/A

**20. CONSENT DOCUMENTS**(a) **Attach an Information Letter/Consent Form**

For details about the required elements in the information letter and consent form, please refer to our informed consent guide ([**http://www.research.utoronto.ca/wp-content/uploads/2010/01/GUIDE-FOR-INFORMED-CONSENT-April-2010.pdf**](http://www.research.utoronto.ca/wp-content/uploads/2010/01/GUIDE-FOR-INFORMED-CONSENT-April-2010.pdf)**)**

**Additional documentation regarding consent should be provided such as:**

* + **screening materials introductory letters, letters of administrative consent or authorization**

(b) If any of the information collected in the screening process - prior to full informed consent to participate in the study - is to be retained from those who are later excluded or refuse to participate in the study, please state how potential participants will be informed of this course of action and whether they will have the right to refuse to allow this information to be kept.

N/A

**21. COMMUNITY AND/OR ORGANIZATIONAL CONSENT, OR CONSENT BY AN AUTHORIZED PARTY**

(a) If the research is taking place within a community or an organization which requires that formal consent be sought prior to the involvement of individual participants, describe how consent will be obtained and attach any relevant documentation. If consent will not be sought, please provide a justification and describe any alternative forms of consultation that may take place.

N/A

(b) If any or all of the participants are children and/or individuals that may lack the capacity to consent , describe the process by which capacity/competency will be assessed and/or, the proposed alternate source of consent.

N/A

(c) If an authorized third party will be used to obtain consent:

i) Submit a copy of the permission/information letter to be provided to the person(s) providing the alternative consent

ii) Describe the assent process for participants and attach the assent letter.

N/A

**22. DEBRIEFING and DISSEMINATION**

(a) If deception or intentional non-disclosure will be used in the study, provide justification. Please consult the [Guidelines for the Use of Deception and Debriefing in Research](http://www.research.utoronto.ca/wp-content/uploads/2009/09/Deception_and_Debriefing_Guidelines.pdf)

N/A

(b) Please provide a copy of the written debriefing form, if applicable.

(c) If participants and/or communities will be given the option of withdrawing their data following the debriefing, please describe this process.

N/A

(d) Please describe what information/feedback will be provided to participants and/or communities after their participation in the project is complete (e.g., report, poster presentation, pamphlet, etc.) and note how participants will be able to access this information.

The results of the data analyses will be posted on the web portal of Black Board.

 **23. PARTICIPANT WITHDRAWAL**

(a) Where applicable, please describe how participants will be informed of their right to withdraw from the project and outline the procedures that will be followed to allow them to exercise this right.

At the end of the assessment, students will be given an option to completely withdraw their data should they feel uncomfortable in their participation. At any given point of taking the assessment, students are also able to withdraw from the study by exiting the browser. Incompletely assessments and withdrawn data will be not be included in the final analysis of the study.

(b) Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

Withdrawn data and incomplete data will not be included in the final analyses of the study data. Participants will not receive any consequences for withdrawing their data at any point of the assessment. The bonus incentive will still be given to participants if they choose to withdrawn their information after they have finished the full assessment.

(c) If participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain. Ensure this information is included in the consent process and consent form.

N/A

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| **SECTION E – CONFIDENTIALITY AND PRIVACY** |

**24. CONFIDENTIALITY**

Data security measures must be consistent with UT's [*Data Security Standards for Personally Identifiable and Other Confidential Data in Research*.](http://www.research.utoronto.ca/wp-content/uploads/documents/2013/05/datasecurity1.pdf) All identifiable electronic data that is being kept outside of a secure server environment must be encrypted.

(a) Will the data be treated as confidential? Yes [x]  No [ ]

(b) Describe the procedures to be used to protect the confidentiality of participants or informants, where applicable

Participants will not be asked of their name, student number, address, or phone number for the purpose of this study.

Student UTORid will be used as username for this study, however this information will be stored on the server as a randomly generated number/letter identifier for the duration of the study. A password-protected MySQL database will contain UTORIDs and all information linked to that ID. Emails will be stored here for password retrieval purposes and for reminders of a student’s unique ID identifier. General information (age, gender, etc), tool-use statistics, and pre-test and post-test scores will be stored in the same password-protected MySQL database. Only Jodie Jenkinson, Gael McGill and Erina He will have access to the databases. The results will be tallied, associated to their unique identifiers, and stored on the secure database. This information will be confidential and not distributed by any means. Personal identifiers (i.e. UTORIDs, emails) will be deleted and disconnected from retrieved data upon completion of the data collection.

Online Database Encryption:

Personal identifiers will be hash-code encrypted using MySQL’s Advanced Encryption Standard (AES) algorithm, which uses a 128-bit key encoder. This algorithm takes a string of characters (like a password) and returns a binary string that is illegible to a viewer. Data stored in the online database resides on BMC’s

MySQL secure server (see section (d)).

Hard Drive Encryption:

Files downloaded from the database will be stored in a single folder on the principal investigator’s personal desktop computer. File Vault (for MacOSX) will be used to secure the downloaded files in this file folder. The principal investigator’s personal computer is itself password protected. Only the principal investigator has

access.

All data (on the databases and on the computer and images) will be permanently deleted upon completion of this project. Online assessment will be taken down from the server upon completion of the study.

(c) Describe any limitations to protecting the confidentiality of participants whether due to the law, the methods used, or other reasons (e.g., a duty to report)

N/A

**25. DATA SECURITY, RETENTION AND ACCESS**

(a) Describe how data (including written records, video/audio recordings, artifacts and questionnaires) will be protected during the conduct of the research and dissemination of results.

MySQL is an open-source relational database management system. All data regarding MySQL users, their computers' system information and benchmark results are stored on the BMC secure web- server. The web application will also be hosted on the BMC server and all interactions between the unity client and the server database will occur through server-side encryption (https). The data collected for this project will be stored on the principal investigator’s password-protected MySQL databases and all personal identifiers will be hash-code encrypted using MySQL’s AES algorithm. Data that is downloaded from the database will be stored on the principle investigator’s personal computer and will be encrypted using File Vault (requiring password for access).

 (b) Explain how long data or samples will be retained. (If applicable, referring to the standard data retention practice for your discipline) Provide details of their final disposal or storage. Provide a justification if you intend to store your data for an indefinite length of time. If the data may have archival value, discuss how participants will be informed of this possibility during the consent process.

When testing is complete, the electronic file containing the participant’s names and email addresses will be deleted. No physical copies of the assessment or consent form will exist in this study. Only summary data of the study will be published.

(c) If participant anonymity or confidentiality is not appropriate to this research project, please explain.

N/A

(d) If data will be shared with other researchers or users, please describe how and where the data will be stored and any restrictions that will be made regarding access.

Data from this study will be only shared with investigators on this same team. The data will be void of any identifiable information linking it back to the participant.

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| **SECTION F – LEVEL OF RISK AND REVIEW TYPE** |

See the [*Instructions for Ethics Review Submission Form*](http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/humans-in-research/) for detailed information about the Risk Matrix.

**26. RISK MATRIX: REVIEW TYPE BY GROUP VULNERABILITY and RESEARCH RISK**

1. Indicate the Risk Level for this project by checking the intersecting box

 **\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_**Research Risk**\_**\_\_**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Group Vulnerability Low Medium High**

**Low** **1** [x]  **1** [ ]  **2** [ ]

**Medium** **1** [ ]  **2** [ ]  **3** [ ]

**High** **2** [ ]  **3** [ ]  **3** [ ]

(b) Explain/justify the level of research risk and group vulnerability reported above:

We estimate the overall risk of this study to be low. Students are not asked to do any tasks that are unfamiliar to their academic curriculum, furthermore they are not evaluated on their performance of this study. The Group Vulnerability is estimated as Low because the proposed participant group is not known to have any pre-existing conditions that would be exacerbated by this study. Participants will be told that any information they provide will not be identifiable. All participants are also told that they may withdraw from the study any point without notice and without the fear of academic penalty.

**(Please note that the final determination of Review Type and level of monitoring will be made by the reviewing University of Toronto REB)**

Based on the level of risk, these are the types of ethics review that an application may receive:

 **Risk level = 1: Delegated Review; Risk level = 2 or 3: Full Board Review**

**For both delegated and full reviews (SSH&E, HS, or HIV)**, please submit one electronic copy of your application and all appendices (e.g., recruitment, information/consent and debriefing materials, and study instruments) as a **single** Word document or a pdf. *Do not submit your entire research proposal.* Please ensure that the electronic signatures are in place and e-mail to **new.ethics.protocols@utoronto.ca**

**The deadline for delegated review (SSH&E or HS) is EVERY Monday, or first business day of the week, by 4 pm. Information about full REB meeting and submission due dates are posted on our website** ([SSH&E](http://www.research.utoronto.ca/about/boards-and-committees/research-ethics-boards-reb/), [HS](http://www.research.utoronto.ca/about/boards-and-committees/research-ethics-boards-reb/) or [HIV](http://www.research.utoronto.ca/about/boards-and-committees/research-ethics-boards-reb/)).

**HIV REB reviews all applications at full board level but applies proportionate review based on the level of risk.**

**All other submissions (e.g., amendments, adverse events, and continuing review submissions) should be sent to** **ethics.review@utoronto.ca**

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| **SECTION G – SIGNATURES** |

 **27. PRIVACY REGULATIONS**

**My signature as Investigator, in Section G of this application form, confirms that I am aware of, understand, and will comply with all relevant laws governing the collection and use of personally identifiable information in research.** I understand that for research involving extraction or collection of personally identifiable information, provincial, national and/or international laws may apply and that any apparent mishandling of personally identifiable information must be reported to the Office of Research Ethics.

For U of T **student researchers**, my signature confirms that I am a registered student in good standing with the University of Toronto. My project has been reviewed and approved by my advisory committee or equivalent (where applicable). If my status as a student changes, I will inform the Office of Research Ethics.

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| Signature of Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:        |

\*\*\*For **Graduate Students**, the signature of the Faculty Supervisor is required. For **Post-Doctoral Fellows** and **Visiting Professors or Researchers**, the signature of the Faculty Sponsor is required. In addition to the supervisor/sponsor, the chair or the dean of the UoT sponsor’s/supervisor’s department is required to approve and sign the form\*\*\*

As the UofT **Faculty Supervisor** of this project, my signature confirms that I have reviewed and approve the scientific merit of the research project and this ethics application submission. I will provide the necessary supervision to the student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with relevant University, provincial, national or international policies and regulations that govern research involving human subjects. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

As the UofT **Faculty Sponsor** for this project, my signature confirms that I have reviewed and approve of the research project and will assume responsibility, as the University representative, for this research project. I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national or international policies and regulations that govern research involving human participants.

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| Signature of Faculty Supervisor/Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:        |

As the **Departmental Chair/Dean**, my signature confirms that I am aware of the [requirements for scholarly review](http://www.research.utoronto.ca/wp-content/uploads/2012/08/Chair-Reps-on-Protocol-REPAC-approved-April-2012.pdf) and that the ethics application for this research has received appropriate review prior to submission.

In addition, my administrative unit will follow guidelines and procedures to ensure compliance with all relevant University, provincial, national or international policies and regulations that govern research involving human participants. My signature also reflects the willingness of the department, faculty or division to administer the research funds, if there are any, in accordance with University, regulatory agency and sponsor agency policies.

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| Print Name of Departmental Chair/Dean (or designate) :      Signature of Departmental Chair/Dean: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      (or authorized designate)  |