Additional file 1: Ethics submission

UNIVERSITY OF TORONTO

OFFICE OF THE VICE-PRESIDENT, RESEARCH AND INNOVATION

Human Participant Ethics Protocol Submission

CONFIDENTIAL

0 - Identification

RIS Human Protocol Number
48358

Protocol Title
Advancing Knowledge and Equity: A Transdisciplinary Approach to Sex and Gender+ Science Across Biomedical, Clinical, Health Services, and Population Health Research

Protocol Type
Investigator Submission

Applicant Information

Applicant Name
Tatyana Mollayeva

Rank / Position
Asst Professor

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Dalla Lana School of Public Health - Dalla Lana Sc

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TATYANA.MOLLAYEVA@UTORONTO.CA

Collaborators/Co-Investigators

Name	Department	Email	Phone	Designation	Alt Contact
Michael Escobar	Dalla Lana School of Public Health	m.escobar@utoronto.ca	(416) 978-7942		
Angela Colantonio	Dept of Occupational Science & Therapy	angela.colantonio@utoronto.ca	(416) 978-7942		
Ibukun Abejirinde	Dalla Lana School of Public Health	ibukun.abejirinde@utoronto.ca	416-978-2011		
Milos Popovic	Institute of Biomedical Engineering	milos.popovic@utoronto.ca	416-594-3422		
Thaisa Tylinski Sant'Ana	University Health Network	thaisa.santana@mail.utoronto.ca	4165973422	Alternate Contact	X

Projected Project Dates

Estimated Start Date
1-May-25

Estimated End Date
31-Aug-25

2 - Location

Location of the Research: ☐ University of Toronto ☒ Other Locations

Other Location Details

Type	Name	Location	Country	Contact	Email	Description

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Hospital	TORONTO REHABILITATION INSTITUTE	Toronto	Canada	Milos Popovic	milos.popovic@utoronto.ca	

Administrative Approval/Consent

Administrative Approval/Consent Needed: ○ Yes ◉ No

Community Based Particatory Research Project? ○ Yes ◉ No

Other Ethic Boards Approval(s)

Another Institution or Site involved? ○ Yes ◉ No

3 - Agreements and Reviews

Funding

Project Funded? ◉ Yes ○ No

Non U of T Administered Funding

Source and Type	Awarded/Applied for	Peer Reviewed
Canadian Institutes of Health Research	Awarded	X

Agreements

Funding/non-funding Agreement in Place? ◉ Yes ○ No

Document Title	Document Date
Decision _CIHR	2024-05-14

Any Team Member Declared Conflict of Interest? ○ Yes ◉ No

Reviews

☒ This research has gone under scholarly review by thesis committee, departmental review committee, peer review committee, or some other equivalent

Type of Review : -e.g.: departmental research committee, supervisor, CIHR, SSHRC, OHTN, etc.

CIHR

☒ This review was specific to this protocol

☐ The review was part of a larger grant

☐ This research will go under scholarly review prior to funding

☐ This review will not go under a scholarly review

4 - Potential Conflicts

Conflict of Interest

Will researchers, research team members, or immediate family members receive any personal benefit? ○ Yes ◉ No

Restrictions on Information

Are there any restrictions regarding access to, or disclosure of information (during or after closure)? ○ Yes ◉ No

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Researcher Relationships

Are there any pre-existing relationships between the researchers and the researched? ○ Yes ◉ No

Collaborative Decision Making

Is this a community based project - i.e.: a collaboration between the university and a community group? ○ Yes ◉ No

5 - Project Details

Summary

Rationale

Describe the purpose and scholarly rationale for the project

Our overarching aim is to strengthen capacity in Sex and Gender+ Science to address pressing health challenges and inequities. To achieve this aim, we have three objectives:
(1) to engage English- and French-speaking stakeholders, including people with lived experience and industry partners, to prioritize topics for the curriculum based on existing knowledge gaps;
(2) to collaboratively develop an interactive curriculum that incorporates diverse voices, experiences, and cultural perspectives to increase the visibility and relevance of Sex and Gender+ Science across four pillars of health research – (i) Biomedical, (ii) Clinical, (iii) Health Services, and (iv) Social, Cultural, Environmental and Population Health Research;
(3) to deliver program in both official languages to increase trainee leadership and visibility through capacity building, cross-pollination of knowledge, and development of actionable steps to advance Sex and Gender+ Science and address inequalities at national and global levels.
We are seeking ethics approval for the training program evaluation, asking trainees, who consented to participate in research, questions assessing whether training program met the learning objectives as outlined in the grant proposal, and whether the program (i) aligned with trainees' learning objectives, (ii) will be useful in their research and/or practice; and (iii) allowed trainees to build meaningful connections with mentors and peers. Open-ended fields prompt for (i) the most useful element of the training program and why, (ii) what could have been done differently to improve program content, structure, and/or delivery, (iii) whether trainees observed any situations during the training program that required more inclusive and/or culturally-sensitive approach, and (iv) other comments and/or suggestions.

Methods

Describe formal/informal procedures to be used

Coordination and management goals for implementation of the 2025 SP Sex & Gender+ include:
(i) maintaining active communication among co-applicants and collaborators;
(ii) ensuring complementarity of program events (e.g. presentations, workshops, and field trips) through their intentional selection and ordering; (iii) monitoring progress of program development against the timeline; and (iv) implementing a standardized process for reporting and other administrative tasks.
Objective 1: Engaging diverse knowledge and perspectives. We will draw upon the recommendations, trainings, and tools of the CIHR, National Institutes of Health (NIH), United Nations (UN),and World Health Organization (WHO) to inform the content of the program. We invited graduate trainees to set learning objectives and indicate perceived knowledge and interest in sex, gender+ applications across pillars of health research. Their responses were summarized by themes (Appendix File 1). This list has been distributed to invited speakers and team members from across the four pillars who are involved in the planning of the event, involved in initiatives incorporating biological sex, sociocultural gender, sex/gender entanglement, and intersectionality, to revise their session titles and learning objectives through the lens of priority setting by trainees. The core team members involved in the grant proposal will note any gaps that need to be filled, and ensure these gaps are covered through reading and discussions.
Objectives 2 and 3: Developing and delivering the program. Guided by the CIHR-IGH, results of Objective 1, leading resources for SGBA+, and invited experts' knowledge in policy and practice, we will develop the content of the educational program. We will cover major frameworks, analytical tools, methodologies (hypothesis- and data-driven), and existing measures to capture biological sex, sociocultural gender, sex/gender entanglements, and intersecting social dimensions relevant to explaining variance in health outcomes. For each construct (i.e., sex, gender, etc.) and each health research pillar, we will cover how sex, gender, and intersectionality processes and factors, independently and/or combined, impact health outcomes. We have compiled the program and speakers for the five day summer institute (Appendix File 2).
To increase trainee leadership and visibility, our proposal includes engaging trainees before they get to the program by completing readings and training modules, as well as introducing themselves online, as we will coordinate a community of practice specific to this summer school. Each trainee will be connected with a core team member (~3:1 ratio) to foster professional development, opportunities for collaboration, and further engagement in Sex and Gender+ Science activities. Throughout the 5 days program, there will be several interactive workshops and networking opportunities for trainees to build their skills and connections. The program will conclude with a synthesis session, key takeaways, and program evaluation.
We are seeking ethics approval for the training program evaluation. We will distribute an online survey in English (Appendix File 3) to trainees via SurveyMonkey. The survey includes Likert scale questions assessing whether training program met the learning objectives as outlined in the grant proposal, and whether the program (i) aligned with trainees' learning objectives, (ii) will be useful in their research and/or practice; and (iii) allowed trainees to build meaningful connections with mentors and peers. Open-ended fields prompt for (i) the most useful element of the training program and why, (ii) what could have been done differently to improve program content, structure, and/or delivery, (iii) whether trainees observed any situations during the training program that required more inclusive and/or culturally-sensitive approach, and (iv) other comments and/or suggestions.

Copies of questionnaires, interview guided and/or other instruments used

Document Title	Document Date
Institute Program Overview and Overarching Themes	2025-03-20

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Document Title	Document Date
Selection of trainees	2024-11-06
Summer Institute - Learning Objectives as Requested by Trainees	2025-03-20

Clinical Trials

Is this a clinical trial? ○ Yes ◉ No

6 - Participants and Data

Participants and/or Data

What is the anticipated sample size of number of participants in the study? 32

Describe the participants to be recruited, or the individuals about whom personally identifiable information will be collected. List the inclusion and exclusion criteria. Where the research involves extraction or collection personally identifiable information, please describe where the information will be obtained, what it will include, and how permission to access said information is being sought.

The sample of this research will be composed exclusively of trainees attending the Summer Institute, which have been selected by the selection committee at the CIHR Institute of Gender and Health. The criteria are outlined on this webpage (https://cihr-irsc.gc.ca/e/53781.html), also included as an Appendix (Appendix File 4). The selection criteria established by CIHR are as follows, extracted from the webpage above:
"The applicant must be a trainee enrolled at a Canadian University. A Trainee: must be registered in a Master's or doctoral program OR be at the post-doctoral or post–health professional degree stage. International students enrolled at a Canadian University are eligible to apply.
The trainee must be committed to attend the entire 5-day program of the 2025 IGH Summer Institute.
In addition:
The trainee must be engaged in research that aligns with the IGH mandate and/or strategic research priority areas of IGH and considers sex as a biological variable and/or gender as a socio-cultural determinant of health as an integral part of the research question(s), research design, methods, analysis and/or data reporting.
IGH is committed to excellence in research and research training. In alignment with the Tri-agency Statement on Equity, Diversity and Inclusion (EDI), this travel award opportunity is committed to increasing equitable and inclusive participation in research training opportunities. As such, a statement outlining EDI-informed considerations that apply to the application must be included (see How to apply section for more details)."

Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulty understanding consent, history of exploitation by researchers, or power differential between the researcher and the potential participant)? ○ Yes ◉ No

Recruitment

Is there recruitment of participant? ○ Yes ◉ No

Is participant observation used? ○ Yes ◉ No

Will translation materials be used/required? ◉ Yes ○ No

Description of translation materials

We will make the evaluation form available in both English and French. The translation will be conducted by a team member who is fluent in French and will verify the accuracy and intended meaning of the translation.

Attach copies of all recruitment posters, flyers, letters, email text, or telephone scripts

Document Title	Document Date
Not Applicable	

Compensation

Will the participants receive compensation? ○ Yes ◉ No

Non Compensation Description

Participants are graduate level trainees who received full funding to attend the 5-day Summer Institute and, therefore, will have no expenses related to participati

Is there a withdrawal clause in the research procedure? ○ Yes ◉ No

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7 - Investigator Experience

Investigator Experience with this type of research

Please provide a brief description of the previous experience for this type of research by the applicant, the research team, and any persons who will have direct contact with the applicants. If there is no previous experience, how will the applicant and research team be prepared?

Dr. Tatyana Mollayeva (PI) holds Canada Research Chair (Tier 2) in Neurological Disorders and Brain Health; Scientist KITE Research Institute, Toronto Rehab-UHN; Assistant Professor (Status) Dalla Lana School of Public Health & Occupational Science and Occupational Therapy, University of Toronto; Atlantic Fellow for Equity in Brain Health, Global Brain Health Institute; Sex & Gender Champion, Women, Sex, Gender, and Dementia Canadian Consortium of Neurodegeneration in Aging (CCNA).
Dr. Angela Colantonio holds Canada Research Chair (Tier 1) in Traumatic Brain Injury in Underserved Populations, former CIHR Research Chair in Gender Work and Health, Professor Rehabilitation Sciences Institute, Department of Occupational Science and Occupational Therapy, Temerty Faculty of Medicine, Dalla Lana School of Public Health, University of Toronto, Senior Scientist and Team Leader, Acquired Brain Injury & Society Team, KITE-Toronto Rehabilitation Institute, UHN, Senior Adjunct Scientist, ICES.
The team has published number pf publications on the topic of sex and gender in traumatic brain injury- most relevant are listed below:
1. Mollayeva T. Synthesizing sex and gender inequities in traumatic brain injury to catalyze inclusive policy and health services initiatives. Med (N Y). 2022 May 13;3(5):289-293.
2. Mollayeva T, Tran A, Chan V, Colantonio A, Escobar MD. Sex-specific analysis of traumatic brain injury events: applying computational and data visualization techniques to inform prevention and management. BMC Med Res Methodol. 2022;22(1):30.
3. Mollayeva T, Mollayeva S, Colantonio A. (2022). The implications of sex and gender in traumatic brain injury. In Traumatic brain injury: cellular mechanisms to medical management. Ed R Rajendram, V Preedy & C Martin. Elsevier Textbook
4. Baldeo N, D'Souza A, Haag L, Colantonio A, Riopelle R, Archambault P, Colquhoun H, Lewko J, Quilico E, Hanafy S, Mollayeva T. (2022). A thematic analysis of patients' and their informal caregivers' gendered experiences in traumatic brain injury. Disabil Rehabil. 2022;1-10.
5. Mollayeva T, Bordignon C, Ishtiaq M, Colquhoun H, D'Souza A, Archambault P, Lewko J, Quilico E, Colantonio A. (2021). Knowledge of sex and gender and related information needs in patients with traumatic brain injury: in-depth interview study. Disability and rehabilitation, 43(13), 1872–1882.
6. Fabricius AM, D'Souza A, Amodio V, Colantonio A, Mollayeva T. Women's Gendered Experiences of Traumatic Brain Injury. Qual Health Res. 2020 Jun;30(7):1033-1044.
7. D'Souza A, Fabricius A, Amodio V, Colquhoun H, Lewko J, Haag HL, Quilico E, Archambault P, Colantonio A, Mollayeva T. Men's gendered experiences of rehabilitation and recovery following traumatic brain injury: A reflexive thematic analysis. Neuropsychol Rehabil. 2020 Sep 22:1-22.
8. Hanafy S, Amodio V, Haag H L, Colquhoun H, Lewko J, Quilico E, Riopelle R, Archambault, P, Colantonio A, Lindsay S, Mollayeva T. (2022). Is it prime time for sex and gender considerations in traumatic brain injury? Perspectives of rehabilitation care professionals. Disability and rehabilitation, 44(5), 684–692.
9. Mollayeva T, Mollayeva S, Pacheco N, Colantonio A. systematic review of sex and gender effects in traumatic brain injury: equity in clinical and functional outcomes. Front Neurol. 2021 Sep 10;12:678971.

Are community members collecting and/or analyzing data? ○ Yes ◉ No

8 - Possible Risks and Benefits

Possible Risks

Potential Risk Details:

Physical Risks	○ Yes	◉ No
Psychological/emotional Risks	○ Yes	◉ No
Social Risk	○ Yes	◉ No
Legal Risk	○ Yes	◉ No

Potential Benefits

Benefit Description

It is widely acknowledged that education represents an opportunity to tackle inequities, reducing biases and boosting positive attitudes to improve equal societies. International organizations' guidelines such as the World Health Organization for instance focus on gender education in the healthcare managers curriculum. The project is supported by the Canadian Institutes of Health Research Institutes of Gender and Health and aims to improve knowledge and skills in research. We are seeking ethics approval to understand the value of out 5-day training institute and evaluate whether the program meets trainees' expectations. This work is essential to improve future capacity building initiatives in Canada and knowledge translation. We do not anticipate any physical, emotional, social, or legal risks associated with the evaluation process.

9 - Consent

Consent Process Details

The survey link begins with a section titled "Pre-Survey Questions: Consent" where we will ask trainees to give their permission to use their responses in

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publication anonymously. We will utilize Survey Monkey's "Question Skip Logic" feature to automatically remove participants did not provide consent, meaning that will be unable to proceed with survey completion.
I read and understood the online Consent Form.
Yes
No
I understand that I can ask questions about the research at any time. How? By contacting the Principal Investigator Dr. Tatyana Mollayeva at tatyana.mollayeva@utoronto.ca
Yes
No
I understand that information that can identify me will not be collected by the research team.
Yes
No
I understand that I can skip survey questions or stop answering the survey.
Yes
No
I understand that once I click "Done" at the end of the survey, my responses will be submitted to the research team and cannot be deleted.
Why? Because information that can link me back to my responses will not be collected, making it impossible for the research team to delete my responses.
Yes
No
I understand that I do not give up any legal rights by giving my consent to participate.
Yes
No
Do you agree to participate in this study?
I agree to participate
I do not agree to participate

Uploaded letter/consent form(s)

Document Title	Document Date
Online Consent Form	2025-03-21
Survey including consent	2025-03-21

Is there additional documentation regarding consent such as screening materials, introductory letters etc.: ○ Yes ◉ No

Uploaded letter/consent form(s)

Will any information collected in the screening process - prior to full informed consent to participate in the study - be retained for those who are later excluded or refuse to participate in the study? ○ Yes ◉ No

Is the research taking place within a community or organization which requires formal consent be sought prior to the involvement of the individual participants ○ Yes ◉ No

Are any participants not capable (e.g.: children) of giving competent consent? ○ Yes ◉ No

10 - Debriefing and Dissemination

DeBrief

Will deception or intentional non disclosure be used? ○ Yes ◉ No

Will a written debrief be used? ○ Yes ◉ No

Do participants/communities have the right to withdraw their data following the debrief? ○ Yes ◉ No

Information Feed Back Details following completion of a participants participation in the project

We will share all published works with all the trainees who attended the summer institute via email.

Procedural details which allow participants to withdraw from the project

☒ Not Applicable

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What happens to a participants data and any known consequences related to the removal of said participant

☒ Not Applicable

List reasons why a participant can not withdraw from the project (either at all or after a certain period of time)

We do not collect personal information. The following wording is given in the consent section of the survey "I understand that once I click "Done" at the end of the survey , my responses will be submitted to the research team and cannot be deleted. Why? Because information that can link me back to my responses will not be collected, making it impossible for the research team to delete my responses." When the participant selects "no", they would be redirected to the exit page, and will be unable to complete the survey.
Additionally, the following text was included in the consent form: “Can participants choose to leave the study?
You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. To withdraw, exit the survey before clicking the “Done” button at the end. This way, your data will not be recorded.
If you decide to leave the study after clicking “Done” at the end of the survey, your data will still be included in the analysis. This is because we do not collect any personal information that would allow your survey responses to be identified and have your data removed.”

☐ Not Applicable

11 - Confidentiality and Privacy

Confidentiality

Is the data confidential? ◉ Yes ○ No

Will the confidentiality of the participants and/or informants be protected? ◉ Yes ○ No

List confidentiality protection procedures

We do not collect identifiable data of individual persons. Survey Monkey collects the IP address of the device a respondent uses to complete the survey. An IP address is a number that identifies a device on the internet. Survey Monkey stores IP addresses for 13 months, however this information is not accessible to the research team. Therefore, the research team will not be able to identify research participants. Your data will be used as described in this consent form.

Are there any limitations on the protection of participant confidentiality? ◉ Yes ○ No

List Confidentiality Limitations

Data collected uses Survey Monkey and no assurance can be made about its confidentiality or that it will only be used for research purposes. Survey Monkey collects the IP address of the device a respondent uses to complete the survey. An IP address is a number that identifies a device on the internet. Survey Monkey stores IP addresses for 13 months, however this information is not accessible to the research team. Therefore, the research team will not be able to identify you.

Is participant anonymity/confidentiality not applicable to this research project? ○ Yes ◉ No

Data Protection

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

We are not collecting any identifiable information.
Data collected uses Survey Monkey and no assurance can be made about its confidentiality or that it will only be used for research purposes. Survey Monkey collects the IP address of the device a respondent uses to complete the survey. An IP address is a number that identifies a device on the internet. Survey Monkey stores IP addresses for 13 months, however this information is not accessible to the research team. Therefore, the research team will not be able to identify you.

Explain for how long, where and what format (identifiable, de-identified) data will be retained. Provide details of their destruction and/or continued storage. Provide a justification if you intend to store identifiable data for an indefinite length of time. If regulatory requirements for data retention exists, please explain.

The data will be downloaded from Survey Monkey and stored at the secure drive at UHN. As soon as it is downloaded from Survey Monkey, we will delete the data from the Survey Monkey website.
We anticipate data analyses will take 6-12 months to complete. The data will be destroyed after we complete data analyses and publish results.

Will the data be shared with other researchers or users? ○ Yes ◉ No

12 - Level of Risk and Research Ethics Board

Level of Risk for the Project

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Group Vulnerability: Low

Research Risk: Low

Risk Level: 1

Explanation/Justification

Explanation/Justification detail for the group vulnerabilty and research risk listed above

Group vulnerability: participants are graduate trainees, who will be fully informed about the nature of the research, how their responses will be used, and their right to refuse participation. Their level of vulnerability is low because their level of education and knowledge of research risks allow them to make informed decision.
Research risk: minimal risk based on the nature of the questions we are asking (i.e., evaluation of the educational program).

Research Ethics Board

REB Associated with this project: Health Sciences

13 - Application Documents Summary

Uploaded Documents

Document Title	Document Date
Decision _CIHR	2024-05-14
Institute Program Overview and Overarching Themes	2025-03-20
Selection of trainees	2024-11-06
Summer Institute - Learning Objectives as Requested by Trainees	2025-03-20
Online Consent Form	2025-03-21
Survey including consent	2025-03-21

14 - Applicant Undertaking

I confirm that I am aware of, understand, and will comply with all relevant laws governing the collection and use of personal identifiable information is research. I understand that for research involving extraction or collection of personally identifiable information, provincial, federal, and/or international laws may apply and that any apparent mishandling of said personally identifiable information, must be reported to the office of research ethics.

As the Principal Investigator of the project, I confirm that I will ensure that all procedures performed in accordance with all relevant university, provincial, national, and/or international policies and regulations that govern research with human participants. I understand that if there is any significant deviation in the project as originally approved, I must submit an amendment to the Research Ethics Board for approval prior to implementing any change.

☒ I have read and agree to the above conditions

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RIS Protocol Number: 48358

Approval Date: 30-Apr-25

PI Name: Tatyana Mollayeva

Division Name:

Dear Tatyana Mollayeva:

Re: Your research protocol application entitled, "Advancing Knowledge and Equity: A Transdisciplinary Approach to Sex and Gender+ Science Across Biomedical, Clinical, Health Services, and Population Health Research"

The Health Sciences REB has conducted a Delegated review of your application and has granted approval to the attached protocol for the period 2025-04-30 to 2026-04-29.

This approval covers the ethical acceptability of the human research activity; please ensure that all other approvals required to conduct your research are obtained prior to commencing the activity.

Please be reminded of the following points:

- An **Amendment** must be submitted to the REB for any proposed changes to the approved protocol. The amended protocol must be reviewed and approved by the REB prior to implementation of the changes.
- An annual **Renewal** must be submitted for ongoing research. Renewals should be submitted between 15 and 30 days prior to the current expiry date.
- A **Protocol Deviation Report** (PDR) should be submitted when there is any departure from the REB-approved ethics review application form that has occurred without prior approval from the REB (e.g., changes to the study procedures, consent process, data protection measures). The submission of this form does not necessarily indicate wrong-doing; however follow-up procedures may be required.
- An **Adverse Events Report (AER)** must be submitted when adverse or unanticipated events occur to participants in the course of the research process.
- A **Protocol Completion Report** (PCR) is required when research using the protocol has been completed.
- If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

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