UNIVERSITY OF TORONTO

OFFICE OF THE VICE-PRESIDENT,
RESEARCH AND INNOVATION

Human Participant Ethics Protocol Submission

CONFIDENTIAL

0 - Identification

RIS Human Protocol Number
49136

Protocol Title
Stakeholder Identification and Analysis for Early Healtjh Technology Assessment of Human Pluripotent Stem Cell-derived Cardiomyocyte Therapies for Heart Failure

Protocol Type
Investigator Submission

Applicant Information

Applicant Name
Samah Hassan

Rank / Position Asst Professor	**Department / Faculty** Inst of Health Policy, Mgmt & Evaluation - Dalla L
Business Telephone 6474698447	**Extension**

Email Address
SAM.HASSAN@MAIL.UTORONTO.CA

Collaborators/Co-Investigators

Name	Department	Email	Phone	Designation	Alt Contact
Valeria Rac	Inst of Health Policy$ Mgmt & Evaluation	valeria.rac@utoronto.ca	4166347245	Alternate Contact	X
Troy Francis	University Health Network	troy.francis@theta.utoronto.ca	6474698447		

Projected Project Dates

Estimated Start Date 23-Sep-25	Estimated End Date 31-Aug-26

2 - Location

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

Other Location Details

Type	Name	Location	Country	Contact	Email	Description
Non-Institutional Field Location			Canada			online surveys and virtual interviews

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
NERFT	Awarded	X

Agreements

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

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.

NERFT

☐ 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

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

Early Health Technology Assessment (eHTA) is a proactive approach to evaluating the potential value, feasibility, and impact of emerging health innovations during the translational phase. In the context of regenerative therapies based on hPSC-derived CMs, eHTA serves multiple purposes . It provides structured, evidence-informed support that can guide research and development (R&D) strategies during the transition phase. It also identifies the conditions under which a technology can be viable, desirable, and sustainable in healthcare systems. Recent advances in eHTA have recommended the engagement of a broad spectrum of stakeholders, in addition to industry, to ensure relevance and alignment with current needs, priorities, and preferences, and to gather diverse perspectives. However, to ensure proper stakeholder engagement and more effective eHTA, we need to systematically identify key stakeholders involved in developing, regulating, and delivering hPSC-based cardiac therapies, and explore their power, influence and roles in shaping evidence requirements or reimbursement strategies. This step is critical to facilitate stakeholder engagement to explore care pathways, unmet needs, and potential barriers to adoption.

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Grutters, J. P., Kluytmans, A., van der Wilt, G. J., & Tummers, M. (2022). Methods for early assessment of the societal value of health technologies: a scoping review and proposal for classification. Value in Health, 25(7), 1227-1234.
Huygens, S. A., Rutten-van Mölken, M. P., Bekkers, J. A., Bogers, A. J., Bouten, C. V., Chamuleau, S. A., . . . van Mieghem, N. M. (2016). Conceptual model for early health technology assessment of current and novel heart valve interventions. Open heart, 3(2), e000500.
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Metrics, I. (2019). for H. & Evaluation. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2016 (GBD 2016) Results.(2017). 5. Institute for Health Metrics and Evaluation Seattle.
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Seyhan, A. A. (2019). Lost in translation: the valley of death across preclinical and clinical divide–identification of problems and overcoming obstacles. Translational Medicine Communications, 4(1), 1-19.
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Yang, L., Soonpaa, M. H., Adler, E. D., Roepke, T. K., Kattman, S. J., Kennedy, M., . . . Linden, R. M. (2008). Human cardiovascular progenitor cells develop from a KDR+ embryonic-stem-cell-derived population. Nature, 453(7194), 524-528.
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Methods

Describe formal/informal procedures to be used

The purpose of this study is to:

- Identify key stakeholders involved in developing, regulating, and delivering hPSC-based cardiac therapies .
- Characterize key stakeholders involved in developing, regulating, and delivering hPSC-based cardiac therapies and their power, influence and roles in shaping evidence requirements or reimbursement strategies.

Participants will include people with lived experience (PWLE) (e.g. patients, family members, carers or representatives of patient organizations), healthcare providers (e.g. health and social care staff), regulators (e.g. ethics bodies), funding organizations (e.g., grants or government), industry (e.g. pharmaceutical companies) and policymakers (e.g., federal or provincial ministries of health) with an interest in the topic.

We will use a mixed-method study design. We will start by a rapid literature review to identify interest-holders' categories and roles. We will search PubMed, ClinicalTrials.gov, Overton Database (https://www.overton.io/), and International HTA database (https://database.inahta.org/), Grey Literature from previous clinical trial protocols and translational research papers on hPSC-CMs therapies, eHTA reports on cell and gene therapies, policy documents and regulatory submissions or patient group publications. We will review previous interest-holders lists and conduct brainstorming sessions with the project team and consult with experts to ensure a comprehensive list. We will also use the snowball technique, where participants will be asked to name other relevant interest-holders at the end of each meeting.

We will also include interviews and online survey questionnaires. Semi-structured interviews will allow interest-holders to share nuanced perspectives, experiences, and priorities relevant to the HTA process and provide additional context or evidence that may not be captured in literature reviews. In the surveys, we will also include open-ended questions where we invite written input and facilitate comment spaces to allow interest-holders to freely express their feedback.

1. Interviews: Open-ended, semi-structured interviews will be conducted using interview guides with stakeholders. The interviews will be conducted virtually over the phone or using Zoom. Interviews will last between 45-60 minutes in duration.

2. Social Network Survey: Surveys, including structured questionnaires to identify relevant relationships and identify priorities, preferences, perspectives, needs

and patterns of communications. In the surveys, we will also include open-ended questions where we invite written input and facilitate comment spaces to allow stakeholders to freely express their feedback. Surveys will only take 20 minutes to complete through RedCap.
Data Analyses: Qualitative data (interviews/surveys) will undergo inductive coding using Braun & Clarke’s six-phase framework, supported by NVivo software. Data analysis will be an iterative process and undertaken using the Grounded Theory method. This will involve systematic coding of data and theme abstraction with the goal of identifying key factors (facilitators and barriers). Quantitative data from surveys, network graphs will be created using the R Software and SNA metrics will be calculated using the “igraph” package. Network communities will be identified using the Walktrap algorithm, which employs random walks on the edges of a network to detect communities, as random walks typically remain within densely connected areas that correspond to those communities

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

Document Title	Document Date
Interview	2025-07-05
Survey questions	2025-07-05

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? 60

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.

Participants to be recruited: All interested stakeholders, who may be interested, may influence or be affected by stem cell therapy for heart failure.
Inclusion Criteria: Participants might include people with lived experience (PWLE) representatives (e.g. patients, family members, caregivers or representatives of patient organizations), healthcare providers (e.g. health and social care staff), regulators (e.g. ethics bodies), funding organizations (e.g., grants or government), industry (e.g. pharmaceutical companies) and policymakers (e.g., federal or provincial ministries of health) with an interest in the topic
Exclusion criteria: Individuals who cannot provide consent, or are non-fluent in English.
If a participant is interested in participating, a request for an email address will be made to be able to send the study information sheet and consent form.
Sample size justification: We will use a purposive and maximum variation sampling strategy to ensure representation across demographics, geography, experience, and role.
For the survey (n=30), For interview (n=30)
Below is a list of our proposed sample size/group

- Regulatory Agency Representative (5-10)
- Clinician/Cardiologist (5-10)
- Persons with lived Experience (PWLE)/Caregivers/Patient Advocate/Representative (5-10)
- Industry/Manufacturing Representative (5-10)
- Ethics Committees (5-10)
- Payer/Insurance Representative (5-10).

We will utilize multiple recruitment methods (e.g., direct outreach for publicly known participants, public calls, partnerships with community organizations, patient groups, patient advocacy organizations and and professional societies, advocacy groups) using our clear, plain-language invitation email explaining the purpose, expectations, benefits, and logistics of participation. We will also use word-of-mouth recruitment or snowball sampling, where participants will be asked to invite others if they think they are involved or affected by the stem cell therapy.

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

Recruitment details including how, from where, and by whom

We will utilize multiple recruitment methods (e.g., direct outreach for publicly known participants, public calls, partnerships with community organizations). First, we will create clear, plain-language recruitment email explaining the purpose, expectations, benefits, and logistics of participation. We will then contact potential stakeholders, leveraging trusted intermediaries (e.g., personal networks, patient groups, patient advocacy organizations and and professional societies, and advocacy groups) to reach specific communities. We will also use word-of-mouth recruitment or snowball sampling through advisory members.
Recruited participants will be asked to either complete an anonymous online survey or schedule a virtual interview via Zoom or by telephone, based on participant preference. In addition, a section at the end of the survey will also ask participants if they are willing to be contacted for a follow-up interview.
Those who are interested in a follow-up interview will be guided to a link to review the consent form, sign it and leave their contact information and availability to schedule a one-on-one interview (not a group).

If a participant is interested in participating, a request for an email address will be made to be able to send the study information sheet and consent form.
Before any data collection, potential participants will receive plain-language consent detailing:
- The study's purpose, methodology, and duration
- Their specific involvement (e.g., interview, survey)
- The right to withdraw at any time.
- Participants will be asked to review the consent and take as much time as they need to sign before participation.

Dr. Samah Hassan will be responsible for recruitment and obtaining consent

Is participant observation used? ○ Yes ● No

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

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

Document Title	Document Date
Email invitation	2025-07-14

Compensation

Will the participants receive compensation? ● Yes ○ No

Type of Compensation

☒ Financial

☐ In-kind

☐ Other

Compensation Justification Details

For surveys, small incentives, including entry into a draw for a CAD $50 gift card, will be offered.
For interviews, a CAD $ 50 gift card to each participant, instead of a gift card draw.
This will be clearly stated in the recruitment materials to encourage participation and increase response rates.

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

Is compensation affected when a participant withdraws?

If participants chose to withdraw, they will not receive the reimbursment

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?

1. Applicant Experience
The applicant has prior experience leading qualitative and mixed-methods research involving key stakeholders across health innovation and policy settings. This includes designing and conducting semi-structured interviews and stakeholder surveys focused on emerging innovations, particularly in ethically sensitive and technologically complex areas such as cell-based therapies. The applicant has co-led a realist review and knowledge user engagement initiative on novel therapeutics, including regenerative medicine, to understand stakeholder perspectives on value, access, and implementation.Dr. Samah Hassan has the TCP2 certificate
2. Research Team Experience
The broader research team includes experts in health technology assessment (HTA) (Dr. Valeria Rac), qualitative methods, and translational stem cell science. Team members have published on stakeholder engagement frameworks, regenerative medicine policy, and clinical translation of stem cell therapies. Collectively, Dr. Rac and Dr. Hassan and Dr Francis have conducted multiple projects involving stakeholder interviews, community advisory panels, and surveys in areas of cardiovascular health, and health system innovation.
3. Experience of Those in Direct Contact with Participants
All team members have received training in culturally safe, trauma-informed, and ethically rigorous qualitative research methods. Where necessary, mentorship from experienced qualitative researcher (dr. Valeria Rac) and content experts will ensure high-quality data collection.

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

Risk Description

Some questions may make the participant feel uncomfortable. They do not need to answer any questions that they do not wish to, and they can withdraw from the study at any time. Participants will be instructed that they can not answer an interview question by saying “pass”.

Potential Benefits

Benefit Description

While there is no direct benefit from being in this study, this study aims to reduce translational uncertainty, foster stakeholder alignment, and ultimately enhance the feasibility and impact of bringing regenerative stem cell therapies to patients with heart failure in Canada. The analysis will provide a comprehensive map of the stakeholder landscape, identifying key actors, their relationships, influence patterns, resource flows, and potential barriers/facilitators for hPSC-CM adoption. This will inform eHTA modeling, evidence generation, decision-making frameworks, and the development of equitable multi-stakeholder engagement strategies to support the responsible translation of hPSC-CM therapies for HF.

9 - Consent

Consent Process Details

Those who are interested in participating will be provided consent. They will be asked to read and provide their consent before proceeding with either completing the survey or scheduling the interview.

For the survey, the consent will be embedded within the survey, and participants will provide implicit consent when they proceed to complete the survey and submit their answers.

For the interview, the consent link will be sent to each participant while booking for the interview.

Uploaded letter/consent form(s)

Document Title	Document Date
Consent f Survey	2025-07-14
Consent for Interview	2025-07-21

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

After the completion of the project, participants will receive a summary of key findings in formats that are accessible and meaningful. These will include:
Plain-language summary reports highlighting key themes from interviews and surveys
Academic outputs (e.g., publications, conference posters) will be shared with participants who express interest

Procedural details which allow participants to withdraw from the project

During recruitment and in the consent form, participants will be notified that their participation is voluntary.
For the surveys, we clarified the statement as follows: You can choose to end your participation in this research (called withdrawal) before survey submission without having to provide a reason. Since surveys are anonymous, you cannot withdraw after submission. Information that was collected after submission will still be used by the researchers in order to answer the research question, but no new information will be collected without your permission after you withdraw from the study.
For interviews, we clarified the statement as follows: You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. Information that was recorded before you withdrew will not be used by the researchers, recordings will be destroyed and no new information will be collected without your permission after you withdraw from the study.

☐ Not Applicable

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

For the surveys, we clarified the statement as follows: You can choose to end your participation in this research (called withdrawal) before survey submission without having to provide a reason. Since surveys are anonymous, you cannot withdraw after submission. Information that was collected after submission will still be used by the researchers in order to answer the research question, but no new information will be collected without your permission after you withdraw from the study.
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☐ Not Applicable

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

☒ 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

The surveys will be uploaded to RedCap, a secure survey platform. All surveys will be anonymous. All surveys will be uploaded once submitted and stored securely on the UofT password-protected OneDrive. This data is expected to be retained for 10 years from the completion of the study. After this time, the study files will be destroyed.
All interviews will be conducted via UofT Zoom account. Transcription will be conducted using the Zoom built-in transcription feature, which is an approved platform for handling audio recordings. All transcripts generated will be reviewed manually by the research team (Dr. Samah Hassan) immediately after transcription. During this review, we will compare the transcript against the audio recording to ensure accuracy and completeness. Any incidental identifiers (e.g., names, locations, organizational details) will be removed or replaced with neutral descriptors. Only de-identified transcripts will be stored securely within the UofT password-protected OneDrive.
Only authorized study personnel (Dr. Samah Hassan, Dr. Troy Francis) will have access to data, and all identified information will be stored securely on the UofT password-protected OneDrive. This data are expected to to be retained for 10 years from the completion of the study. After this time the study files will be destroyed.

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

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

Digital data (e.g., audio recordings, transcriptions, survey responses) will be stored on encrypted, password-protected servers affiliated with the University of

Toronto institution. Access will be restricted to authorized members of the research team.
Physical data (e.g., consent forms, handwritten notes) will be securely stored in locked cabinets within secure research offices.
Audio and video recordings will start after the participant confirms identification so that recordings are de-identified for transcription.
Questionnaire data will be anonymized, with all identifiers removed or replaced with participant codes before analysis.
During dissemination, only aggregated or anonymized findings will be reported. No identifiable information will be shared in presentations, publications, or other outputs unless explicit consent has been obtained.
All data handling procedures will comply with the Tri-Council Policy Statement [TCPS 2]).

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.

All interview records and survey documents pertaining to the study will be kept by the Principal Investigator on a secure server. This data are expected to to be retained for 10 years from the completion of the study. After this time the study files will be destroyed.

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

Group Vulnerability: Low

Research Risk: Low

Risk Level: 1

Explanation/Justification

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

This study involves interviews and/or surveys with stakeholders such as clinicians, researchers, policymakers, patients/caregivers, and industry representatives regarding their perspectives on stem cell therapies for heart failure. The level of research risk is considered low as there is a non-invasive data collection: The study does not involve any physical interventions or medical procedures. Data will be collected through voluntary interviews and/or questionnaires.

Research Ethics Board

REB Associated with this project: Health Sciences

13 - Application Documents Summary

Uploaded Documents

Document Title	Document Date
Response to REB Comments	2025-11-27
Consent for Interview v2 tracked	2025-11-27
Consent for Survey v2	2025-11-27
Consent for Interview v2	2025-11-27
Consent for Survey v2 tracked	2025-11-27
Interview	2025-07-05
Survey questions	2025-07-05
Email invitation	2025-07-14
Consent f Survey	2025-07-14
Consent for Interview	2025-07-21

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

UNIVERSITY OF
TORONTO

OFFICE OF THE VICE-PRESIDENT,
RESEARCH AND INNOVATION

RIS Protocol
Number: 49136

Approval Date: 8-Dec-25

PI Name: Samah Hassan

Division Name:

Dear Samah Hassan:

Re: Your research protocol application entitled, “Stakeholder Identification and Analysis for Early Healtjh Technology Assessment of Human Pluripotent Stem Cell-derived Cardiomyocyte Therapies for Heart Failure”

The Health Sciences REB has conducted a Delegated review of your application and has granted approval to the attached protocol for the period 2025-12-08 to 2026-12-07.

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.