

| | |
|--------------------------------|---|
| Joint Guidance Document | REB Handbook - Faculty of Arts and Humanities (and related disciplines) |
| Effective Review | NMREB |
| Version Date | July 15, 2022 |

Contents

| | |
|--|----|
| Introduction | 2 |
| PART ONE..... | 4 |
| Section 1: Definitions and Applications | 4 |
| Research..... | 4 |
| Creative Practice..... | 5 |
| Human Participant..... | 7 |
| Secondary Data | 10 |
| Section 2: Recruitment and Consent Considerations | 13 |
| Recruitment: specifics..... | 13 |
| Consent: specifics | 14 |
| PART TWO..... | 16 |
| Section 1: Preparing for REB Review | 16 |
| Mandatory human research ethics training..... | 16 |
| Confirming Research Eligibility..... | 16 |
| Determining board and level of review | 16 |
| Managing timeline expectations | 17 |
| Section 2: Submitting the REB Application | 17 |
| Creating an online application via WREM..... | 18 |
| Describing your project..... | 18 |
| Responding to REB recommendations | 18 |
| Section 3: Post-Approval Review Requirements..... | 19 |
| Amendments..... | 19 |
| Reportable Events | 19 |
| Continuing Ethics Review..... | 20 |
| Study Closure | 20 |
| Appendix 1: Checklist for Determining if REB Review is Needed | 21 |
| Appendix 2: Recruitment Sample..... | 23 |
| Appendix 3: Letter of Information and Consent (LOI/C) Document Checklist | 24 |

| | |
|--|----|
| Appendix 4: Translating the NMREB Initial Application..... | 26 |
| Appendix 5: WREM Resources | 31 |
| Appendix 6: New Projects - WREM Applications..... | 32 |
| Appendix 7: Post-Approval Events (WREM Sub-Forms) | 33 |
| Appendix 8: Relevant Institutional Policies..... | 34 |
| Appendix 9: External Resources..... | 35 |
| Appendix 10: References | 36 |

Authors:

Katelyn Harris, Non-Medical Ethics Office, Office of Human Research Ethics, Western University

Kim Solga, PhD, Department of English and Writing Studies, Western University

Committee Members:

Katelyn Harris, Staff chair, Office of Human Research Ethics

Kim Solga, Faculty chair, Department of English and Writing Studies

Ileana Paul, Department of French Studies

Andrew Walsh, Department of Anthropology

John Hatch, Department of Visual Arts

Karin Schwerdter, Department of French Studies

Michael Fox, Department of English and Writing Studies

Chris Gittings, Department of English and Writing Studies

Margherita Papadatos (grad student), Department of Visual Arts

Sheetala Bhat (grad student), Department of English and Writing Studies

Sandra Smeltzer, Faculty of Information & Media Studies

Karen Kueneman (RO), Faculty of Law, Faculty of Music, and Faculty of Information & Media Studies

Gabrielle Whitlock (RO), Faculty of Arts and Humanities

Introduction

This handbook has been prepared for researchers working in the arts and humanities, broadly defined; its goal is to help researchers with and without prior experience in seeking human ethics approval to understand how the ethics guidelines by which Western University is bound may apply to their research. It has been prepared by Kim Solga, Faculty of Arts and Humanities, and Katelyn Harris, Office of Human Research Ethics, in consultation with a committee representing faculty, staff, and graduate

students in Western's Faculties of Arts & Humanities, Information and Media Studies, Music, and Social Science. In other words: it was created by arts and humanities researchers, with arts and humanities researchers and their specific needs top of mind. The primary objective at the beginning of this collaboration was for mutual learning and we hope that the resulting handbook serves as a foundation for continued education among us all.

Like all universities in Canada, all research at Western University (whether Tri-Council-funded or not) falls under the jurisdiction of the Tri-Council Policy Statement on "Ethical Conduct for Research Involving Humans," known as TCPS2. The Tri-Councils (SSHRC, NSERC, CIHR) sponsor significant amounts of our research, whether we hold Council-named grants or not, and thus it is the responsibility of the university as a whole to ensure that all formal research and publication undertaken by its staff, faculty, and students is consistent with TCPS2 human ethics guidelines. TCPS2 also represents best practice in the field of human research ethics, and thus makes a valuable baseline against which to measure one's own ethical conduct as a researcher.

We understand that not all researchers at Western have a comprehensive familiarity with TCPS2, or best ethics practices generally, because our training varies widely, discipline by discipline, and even institution to institution. Many of us may never have had to apply for ethics approval for a research project, because we do not work with human subjects (preferably known as 'participants') as part of our research; others among us may indeed have worked with human participants for example if we have interviewed an author or used materials from an artist in our research but may not have been aware that the work we undertook falls under the umbrella of "research involving humans". This is not an uncommon situation, and for some of us our first introduction to human research ethics is accidental and can spark anxiety or even panic.

Compounding the problem of varying levels of experience with ethics processes is the nature of TCPS2: like many ethics policy guidelines, it may seem to be written primarily from a biomedical and/or social-science perspective, with health and/or science-side researchers in mind. This means arts and humanities researchers may perceive the document to be biased against them, or impenetrable, or otherwise not applicable, dismissing its utility in the process. This challenge is very understandable, and it is one that this handbook specifically seeks to mitigate.

Below, you'll find a two-part handbook addressing some practical considerations regarding research ethics, separated by key concepts. The first part begins with explanations, examples, and case studies of key terms in TCPS2 and parses the difference between the Policy's understanding of these terms relative to an arts and humanities researcher's own; this section is designed to make the applicability of TCPS2 to your research, or not, much clearer, and easier to estimate. The second section of Part One explains what recruitment and consent processes are expected by TCPS2 and offers tips and wise practices for preparing a Research Ethics Board (REB) application; this section is designed to help you understand how to shape your recruitment and consent processes in a way that allows them to be TCPS2-compliant, even when you're working with colleagues or artists.

Part Two is specifically for those who, based on Part One, have determined that REB review is needed for your project. This part of the handbook provides a detailed overview of the research ethics review process here at Western and has been designed to support arts and humanities researchers successfully navigate this process.

Additionally, the handbook ends with several appendices of supporting resources. Many of these resources specifically pertain to conducting research involving humans at Western. However, it is important to point out that Western's arts and humanities scholars are not alone in recognizing their need to tease out these important issues. Some tips, best practices, and publications pertaining to research ethics in these disciplines from other post-secondary institutions have been included as well. You are encouraged to review these resources, and to consult the literature for yourself too!

Finally, you may also refer to the Table of Contents at any time for quick access to a given section/appendix.

PART ONE:

Below you will find two sections discussing what everyone in arts and humanities side disciplines needs to know about research ethics review. The first section will discuss a number of relevant definitions which will help arts and humanities researchers understand the nuances of their projects and distinguish between scholarly activities requiring research ethics oversight from those that do not.

Section 1: Definitions and Applications

TCPS2 requires that researchers seek approval from their university's Research Ethics Board (REB) when undertaking "activities defined in this Policy as 'research' involving 'human participants.'" Because TCPS2 primarily uses biomedical and social science models and terminology, it's necessary for us in the arts and humanities to understand what, exactly, TCPS2 means by both "research" and "human participants," and how its definitions apply to us.

Research

This is the TCPS2 definition of "research"; it governs all formal ethics review processes.

For the purposes of this Policy, "research" is defined as **an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation**. The term "disciplined inquiry" refers to an inquiry that is conducted with the expectation that the method, results and conclusions will be able to withstand the scrutiny of the relevant research community.

This definition is purposefully broad, in order to encompass many different kinds of "disciplinary" inquiries; however, the TCPS2 understanding of what it means to "extend knowledge" or investigate something systematically can at times be at odds with those of arts researchers.

For TCPS2, for example, the making of an art object or the writing of a novel or short story does *not* qualify as "research", even if undertaken by a university researcher or if counted as research by a collective agreement or tenure committee, because it does not "extend knowledge" in the way TCPS2 uses this phrase. This is true even if the making of the art object or the writing of the novel or short story includes consultation with "human participants" as part of the creation process. TCPS2 expects that, in these cases, creators of art objects will abide by the formal or informal ethics practices that govern artistic creation in their fields.

What this means is: when asking the question "does this project I'm beginning need ethics review?" the most important question you can ask yourself is: "is this project 'research', according to TCPS2, or does it count for TCPS2 as 'creative practice?'"

Creative Practice

TCPS2, in Article 2.6, makes a specific exemption from ethics review for what it calls “creative practices” — what we might, for simplicity, define as “making art without also doing research with or about it.” Here is TCPS2’s definition of “creative practice”:

Creative practice is a process through which an artist makes or interprets a work or works of art. It may also include a study of the process of how a work of art is generated. Creative practice activities do not require REB review, but they may be governed by ethical practices established within the cultural sector.

There are a number of considerations to factor here.

First and foremost, the creative practices exemption means that a researcher interpreting a piece of art—writing, for example, a textual analysis, or close-reading a photograph or a theatre performance does not require ethics approval in order to undertake their investigation. (TCPS2 does not consider “close reading” to be research again, here, we see how disciplinary differences can create challenges when parsing TCPS2’s terminology.) This is true whether an artist is interpreting their own work, or whether a researcher, working with an artist, is interpreting their work in a collaborative undertaking.

Second, the creative practices exemption means that researchers exploring art-making processes for example, by consulting archives, confirming date and location details of rehearsals with stage management, or interviewing a senior artistic director about best practice at his or her venue may well not require ethics approval; in these cases (and “may” is the operative word in the prior statement), **the question of whether or not the REB should be consulted comes down to how human participants outside of the art-making process are involved.** This will be explored in detail in the next section of the handbook.

Third, the creative practices exemption does not absolve practitioners or those interpreting their work from putting good ethics protocols in place; these may be requested by the practitioner involved in the project, may be agreed by both parties, and may be formally agreed or informally understood. The sole consideration here is this: **because TCPS2 distinguishes between “creative practice” and “research” for the purposes of university due diligence, it does not require those undertaking the former to consult the REB.**

For many of us involved in arts and humanities research in the twentieth century, this distinction is increasingly out of date, and out of touch with our own disciplinary formations. Certainly, for those of us engaged in **“practice-based research” or “practice-as-research” (PBR or PaR)**, not only are these TCPS2 distinctions between research and creative practice problematic intellectually, but they can make it very difficult to figure out whether or not the creative practices exemption applies.

In cases where PBR or PaR work blurs the line between “research” and “creative practice” as defined by TCPS2, this is the most important piece of information in Article 2.6:

Creative practice activities, in and of themselves, do not require REB review. However, **research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question** is subject to REB review.

Case Study #1: Research? Creative Practice? Practice-based Research? Parsing the difference.

Back in 2019, there was a production at the Grand Theatre called “This London Life”. It didn’t quite do what it said on the tin; it didn’t really represent the city in all of its wonderful complexity. You’re a writing professor with an interest in theatre, and you decide to create your own play of a similar name in an effort to tell a better London story.

You decide to use a technique called “Verbatim” theatre: plays that use the real words of real humans to puzzle together a kind of “documentary” script. (Think “The Laramie Project” or “London Road”.) You decide you will interview folks in London’s arts community, in order to understand the cultural landscape of the city; then, you’ll introduce teachers at schools, and some of the city’s business leaders too. You’ll ask their permission to use their words in the creation of your script, of course. But if this is a piece of theatre that you plan to stage, does it need UWO’s REB’s ethics approval, formally?

According to the Panel on Research Ethics, “[i]f an activity is being carried out as a form of expression for an artistic purpose, e.g., a theatrical work or video that involves interviewing people, then it is creative practice even if research methods, such as questionnaires, are being used, and even if a form of knowledge is being generated.” This means that if you are pursuing this project purely in order to make a work of art (i.e., the play you’re crafting), you **do not need** REB approval, even though you will obviously need to consider the ethical implications of the Verbatim form as you work with your interview participants on the script. But that ethical consideration can be in fact, separate from the formal ethics review process at UWO, because if you’re just making a play as art, that’s creative practice.

At the same time, according to the PRE, “[i]f the activity is being done for research purposes then it is considered research, even if creative practice methods are being used.” Here’s where you’ll want to ask yourself some questions. You’re creating a play because writing is part of your artistic as well as your professional academic life. What is the purpose of the play? Is your intention to *extend knowledge* on the real-life experiences of those in London through the performance, that is, to investigate and follow up on audience responses, or generate further research into audiences’ own urban experiences? Will you want to discuss this play, its impetus, its methods, perhaps its outcome? in a research document? Will you be interested in writing an article about its creation, or about its reception? Will you be documenting the process in order to reflect on it in relation, for example, to the Grand show that sparked your initial interest? If any of these outcomes seem possible, your play may actually be a form of research-creation and SSHRC considers research creation always to be research. That means, under our obligations to TCPS2, **you may need ethics approval** for the project.

Now it’s not uncommon for artist-scholars to make work in one moment, and then return to it later with an eye to research possibilities around it but we may not have even the slightest inkling at the beginning of a project what such research might end up looking like. And of course, depending on the context surrounding your future reflections on an artistic project, those reflections might actually be covered under TCPS2’s creative practices exemption for example, if you are reflecting as an artist on your earlier body of work, or discussing works you have made from the perspective of a literary interpreter. In a case like the one discussed above, where human participants play a complex role in the creation of work that may or may not become research at some point, it’s always best to query the Office of Human Research Ethics at the beginning of the project, and to seek advice from members of the REB community who have specific experience with this kind of research-creation work.

Additionally, according to the Panel on Research Ethics (PRE) interpretation of creative practice, “[w]hen the activity has a dual purpose of research and creative practice, REB review is required” (Government of Canada, 2021). PRE goes on to explain both that “[i]f an activity is being carried out as a form of expression for an artistic purpose, e.g., a theatrical work or video that involves interviewing people, then it is creative practice even if research methods, such as questionnaires, are being used, and even if a form of knowledge is being generated” AND “[i]f the activity is being done for research purposes then it is considered research, even if creative practice methods are being used.” According to PRE, “[t]he final assessment of whether an activity is research is the responsibility of the REB, in collaboration with the individual proposing the project, and must be made in the context of the specific project under consideration.”

Important Note regarding **Research-Creation (sometimes called “practice-based research (PBR)” or “practice-as-research (PAR)”**: SSHRC considers research-creation projects to be *research* (Government of Canada, 2016), and as such, REB considerations will apply *if* human participants are involved. As such, one of the best ways to understand the applicability of TCPS2 Article 2.6 is to turn to TCPS2’s definition of “human participant.”

Human Participant

TCPS2 defines human participants like this:

For the purposes of this Policy, “human participants” (referred to as “participants”) are those individuals whose data, biological materials, or responses to interventions, stimuli, or questions by the researcher, **are relevant to answering the research question(s)**.

Note that this does *not* mean that any human being contributing every kind of possible data to a study qualifies as a “participant” for ethics review purposes. There are several cases in which information from or about a living human may be obtained by a researcher without requiring REB approval.

The first of these cases is when the information obtained **is in the public domain, and/or the human from whom information is deliberately gathered has no reasonable expectation of privacy**. This is one of the most important factors distinguishing “participants” from others, and it accounts for the exemption Article 2.6 makes for those interpreting works of art. (Art works are inherently understood to be public, and their interpretation is recognized to be the privilege of anyone interested in them.)

The second of these cases involves **observing human interaction in public spaces**, when the researcher has not attempted to manipulate that interaction in any way, and when the humans being observed have no reasonable expectation of privacy (for example, they are not making an active effort to be unseen or unheard in public).

The third of these cases is when the information obtained, whether fully “public” or not, **can be understood to be providing material that is not personal** to the human providing it, nor to those on whose behalf the human speaks, but which can assist in the advancement of the research study, nonetheless.

In all these cases, the easiest way to distinguish between whether or not the humans involved in your research qualifies as a “participant” is to ask this question: ***am I using humans in my work as a RESOURCE for information, or as a SUBJECT of inquiry?***

Examples of using a human as a resource might include:

- Querying an archivist about available materials and the history of those materials' use by the artist(s) involved with it; in this case, the archivist is providing information freely available to the public served by them, even if that public is restricted to qualified researchers seeking permission to attend the archive;
- Asking a question of an author at a book launch, when that book launch has been advertised as open to the public; in this case, the writer's answer enters the public domain, and is therefore freely available to all present for quotation;
- Observing an audience at a theatre performance, and then speculating about the performance's efficacy based on audience reaction. (In this case, information collected is anonymous and public, two criteria for exemption under TCPS2);
- Consulting with resident curators about technical details during the preparation of a gallery exhibition that is being mounted as part of a larger practice-based research project; in this case, the curators are providing a professional service, even if those details end up informing the exhibition's reception or interpretation by others;
- Visiting an Indigenous community, by invitation, to talk informally with elders about drumming circle practices, as part of very preliminary investigation toward a new research project. TCPS2 allows for this kind of early investigatory work before a project gets off the ground for purposes of community engagement, relationship building, and project design. However, TCPS2 stipulates those discussions held before the research work (and participant involvement) becomes formalized cannot be used toward research outcomes. And, of course, in a case like this, researchers would want to observe all Indigenous community protocols on the community's own terms at this early stage, and throughout the research.

By contrast, the humans referenced above become "participants" in these examples:

- While visiting the archive, you involve the archivist in a discussion about their personal experiences of seeing live the works of art you are investigating, and you take notes about their impressions alongside your own;
- The book launch event at which you query the author is closed to the public, but you note the author's answer and intend to use it later as part of your analysis of their work;
- You conduct impromptu "exit interviews" with specific audience members, asking them about how they felt and what they saw, and note their responses, which you use to inform analysis later;
- During your technical consultations with the curators, they become involved in your creative process to the extent that it impacts your research about the process, and in your subsequent research work about the exhibition you incorporate data from their consultations;
- You choose not to pursue the project with the Indigenous community after all, but in a related article for publication you'd like to cite observations from your preliminary research to support your arguments.

From the discussion and examples above, we can see that there are some clear-cut cases where an arts researchers' practice is obviously exempt from REB review and not subject to TCPS2. At the same time, however, there are many instances when the applicability of TCPS2 and REB protocols to our research is

not clear at all, especially as more and more of us undertake projects that blend “creative practice” and “research” in ways TCPS2 doesn’t always anticipate.

Summary Case Study 2: Conversations with Playwrights

To illustrate, here’s an example of the creative practice exemption in action. Then, read on to see when and why it might ‘tip the balance’ to requiring REB review.

Imagine that you are a doctoral student exploring a narrative discourse on transitional justice. You are interested in speaking with a few playwrights whose plays capture the essence of your research topic. The playwrights agree to share with you their respective plays, and they offer you the opportunity to reach out again with any additional questions.

You wonder: “If I talk with these playwrights, do I need REB approval? The interaction would resemble an interview setting...”

So, you contact the Office of Human Research Ethics (OHRE) to learn more.

The OHRE consults with an expert on their Non-Medical REB, who responds: “It sounds like the artists would be speaking about their own creative work, and presumably answering questions related to its development; in that regard, this is covered by the Creative Practice (CP) exemption in the Tri-Council Policy Statement, Article 2.6.”

The expert goes on to explain: “To elaborate, if the topic of conversation remains on the plays and their development, that is focused on the artists talking about the making of their own work, this is CP-exempt. However, if the topic of conversation is intended to include a broader discussion of the playwrights’ body of work, their influences, etc. ranging into “artist as participant” territory (as compared to “artist as resource”), then this will require delegated review.”

Note how the researcher has the autonomy to decide at the outset of their project the intended scope of their potential conversations with the playwrights, considering their research objectives. Provided the nature of the information sought by the researcher stays within the bounds of CP, then no REB oversight is needed. If, based on the research objectives, the researcher may be interested in delving deeper into the playwrights’ experiences beyond the narrative texts, play development, etc., with a focus on the artist more personally, then they would engage the REB review process so that they can explore their research from the perspective of the human participant, beyond the creative practice.

As mentioned above, a key component to understanding the applicability of TCPS2 guidelines is the involvement of human participants. It is important to know when you might be involving human participants in your research because this has direct implications for your REB approval. The general rule of thumb is that REB approval is needed prior to any interactions with human participants for research purposes.

You might be asking yourself, “...wait - how can I get REB approval to use my informal discussions with these people if the opportunity to use their contributions in my work was an afterthought?” or “I didn’t realize I would have X opportunity to talk with Ms. Y...what now?” Great questions!

First, let’s clarify that if you know going into any interaction with others that your intention is to gather insights from them as participants to answer your research question, then you need to obtain formal

REB review and approval of your plan prior to engaging in that work. Here, it is important to be mindful of your research interests and objectives and carefully consider possible 'data sources' for carrying out your work. If they involve human participants, then REB review is needed as soon as possible.

If, on the other hand, by nature of your day-to-day experiences, for example, you happen to obtain information from other peoples' perspectives that you later think you'd like to use in your research, then this information would be called, 'secondary data'.

Secondary Data

TCPS2 talks about three types of secondary data: anonymous, non-identifiable, and identifiable.

Article 2.4 states,

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

In the context of arts and humanities research, anonymous secondary data sources could include:

- Your observations of the audience's reactions at a public performance;
- Overhearing a random comment at a public art event that sparked your interest for a later project;
- Finding a weathered old diary in an abandoned cabin in the forest without any identifiable information or indication who the author might be.

Article 5.5B discusses the use of secondary non-identifiable information:

Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable [anonymized or coded] information [when the key to the code is not accessible].

This could include, for example:

- Requesting to use your colleagues' anonymized interview transcripts from a prior research project in order to answer your research question;
- Obtaining de-identified data from several opera houses who collect information on their season ticket holders as part of their quality assurance initiatives because you are interested in exploring as part of your research the demographic characteristics of those interested in this form of performance arts.

Article 5.5A outlines the requirements for the secondary use of identifiable information:

Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied the REB [that a number of criteria outlined in TCPS2 and prompted in Western's REB application have been adequately addressed].

In short, unless the secondary information is anonymous, REB review will be needed to include secondary data for research purposes. That is, if identifiable, anonymized or coded information is gathered for reasons other than research, which a researcher would like to use for research purposes at a later date, then REB review is needed prior to the **use** of that *already-collected* information. From the list of examples above, this might include:

- The unexpected discussions with the archivist;
- The author's answer to your question at the closed book launch, or during a private conversation with the author after the launch ends;
- The curator's contributions to your exhibition, which you later decided to incorporate into your research;
- The preliminary discussions with members of the Indigenous community who you engaged prior to planning a research project with them, that you have now decided to incorporate into a paper.

As part of the REB review process, you may need to reach out to those people for their consent to include what you learned from them in your research. This decision would depend entirely on the specific circumstances pertaining to your project and your participant(s), and the way in which the original 'data' was collected. As well, the REB would take into consideration your ability to contact such people again to seek their permission to use their reflections in your own work, any implications of using their contributions in your work, and any measures in place to protect their identities (if applicable).

When in doubt about whether your work qualifies as "research" or "creative practice," or whether the humans engaged in your work are "resources" or "participants," and/or whether your project is utilizing primary data or secondary data, it's best to consult the TCPS2 (see Chapter 2) and query the Office of Human Research Ethics directly for assistance. The Non-Medical Research Ethics Board (NMREB) at Western includes several arts and humanities-side researchers, and they will be brought in to assist you as needed.

SUMMARY CASE STUDY 3: IN THE ARCHIVES

Let's review what we've learned with an example.

Above, we make occasional reference to a hypothetical situation where someone is working in an archive, falls into conversation with the archivist, and later wants to use information from that conversation in their research.

What might this scenario look like from start to finish, and what REB-related steps will it occasion?

Imagine you've traveled to the archives at the Stratford Festival to look at materials related to a performance – costumes, script bible, archive video recording. While you're there, you learn that the archivist saw the performance many times – her son was an extra. Curious about her experience as an audience member, and her son's insider experience, you ask her to join you for a coffee break and begin asking her questions that let you compare her experience of the show to yours.

This is a typical situation to fall into: you have had a shared experience, would like to talk about it, and it's time for a break anyway. At this point, you aren't necessarily thinking about how the archivist's perspectives might impact your research directly. You're letting her impressions as a fellow audience member influence yours, same as you might at any other theatre performance.

But what she has to share piques your interest and you can already see how her impressions are changing your interpretation of moments you observed on the performance's archive video. When you get back to your desk, you make some notes; then you get back to your scheduled tasks.

When you return to campus and start the process of writing up your research into the article you have planned about the production, you re-read your notes and remember your chat with the archivist. You realize that her comments bear reference in your paper, and that her son's insights as a performer might be worth following up on.

NOW is the time to notice that the archivist has been an informant for your research, and that to reference your notes from that conversation, or to quote her directly, will require both REB review and her informed consent.

What do you do next?

First, it's important to remember that you've done absolutely nothing wrong; you were carrying out research without human participants that, according to TCPS2, did not require REB review. (You were consulting documents in the public domain at an archive and reflecting on your own experiences of a recorded performance, which falls under the Creative Practices exemption.) You could not have known the archivist would become an informant, and given the circumstances of your chat, you could hardly have been expected to turn down a chance to learn her impressions of the show you both saw while you had her handy.

After you've remembered this, it's time to contact the Office of Human Research Ethics and speak to an Ethics Officer (EO) about the situation. They will let you know that you've collected **secondary data**, which is absolutely allowable, but because it is not anonymous data, there is a process you will need to follow to get ethics clearance before you can complete and publish your article.

Further, you will want now to review what you learned from the archivist about her son's experience, and to separate out information that could be considered her son's proprietary impressions, which he may not have had a reasonable expectation of his mom sharing with a researcher.

Depending on the ways in which you would like to use the information the archivist offered, you may find yourself now taking different steps.

- If you only want to reference the information you already have, information that is based on the archivist's own impressions only, you will need to submit an REB application detailing your plan to contact the archivist with a letter of information and consent form specifying how you would like to use her comments in your research.
- If you'd like to collect more information from the archivist, and perhaps even speak directly to her son, you would need to submit an REB application detailing your plan to conduct a separate, new interview with each of them and in that case you will need to produce a recruitment script and an interview script for the REB to review, along with a letter of information and consent.
- Depending on the son's age, it will also be important to consider that TCPS2 has specific guidelines around conducting research with children (see TCPS2 Chapter 3 on Decision-Making Capacity).

Again, the EOs are available to answer any questions you may have and will be able to offer support in any of these scenarios. Important: Contact them ASAP if time is of the essence, so they can help you move as efficiently as possible through the review process (so that you can still meet your article deadline).

Read on now to learn more about the processes of recruitment and consent that are required by TCPS2.

Section 2: Recruitment and Consent Considerations

Once you determine that your project is subject to TCPS2 and requires REB review, it's important that you have processes in place for recruiting/contacting participants and documenting their consent that conform to the required ethics protocols.

In some ways, the recruitment of human participants for a study in the social sciences can look different from that in the arts and humanities; for example, large social science studies may use dozens or hundreds of participants, consult with each only once (and perhaps then only through a survey or interview), and then anonymize all their data. In the arts and humanities, it's more common for human participant numbers to be smaller, for participants to be already known to researchers (and perhaps even be friends or collaborators with them), and for data to be harder to anonymize. However, arts and humanities research may still involve mass surveys (e.g., perceptions from the audience at a music event) or interviews with people who are not personally known to the researcher (e.g., famous artist contacted through their publicly available contact information).

Regardless of the methodologies used, it is important to know that this variation is common and even standard across disciplines and complies with TCPS2; remember that "research" according to the definition above operates in accordance with methods and standards of evaluation specific to a researcher's field.

However, because of the potential ethical implications of smaller sample sizes, perceptions of obligation among friends/colleagues, and limitations to confidentiality, arts-side researchers using such designs need to explain as fully as possible the reasoning behind their discipline-specific methodological decisions. This includes context-specific recruitment protocols and methods for documenting consent, and any measures in place to ensure voluntary and fully informed participation.

Recruitment: specifics

After determining who you will be including as participants in your research, you'll need to think about how you're going to invite them to participate. For example, do you already have their contact information? Might you run into them at a concert? Is their contact information publicly available? Maybe your colleague or friend has the connection and has offered to introduce you?

Best practices in human research ethics require that recruitment is voluntary, and respect for persons ensures that no one feels obligated or pressured to participate. It is important to be mindful of how you will engage the initial invitation to participate in the research - whether you personally know the potential participant(s) or not (as each scenario may introduce different ethical complexities to consider).

Human participants also need to be given as much information as possible about the study they are asked to be a part of before they can consent to participate; TCPS2 indicates informed consent begins at recruitment. The REB application you'll be filling out will require documentation of your proposed recruitment plan, along with a recruitment script. Near the end of this package is a sample recruitment script (see Appendix 2); it includes the kinds of information that you will need to communicate to your potential participants upon inviting them into the research.

Your recruitment script need not be formal; for example, if you are interviewing a well-known pianist whom you met through a colleague at a conference, it may be appropriate to use informal language consistent with how you might communicate with them for non-research-related purposes. The key is

that you communicate to them a brief description of your project, a summary of what you are asking of them, and how they can learn more if they're interested in participating.

As part of this process, you will need to share with the pianist what's called a Letter of Information (LOI), detailing everything TCPS2 tells us participants need to know to make an informed decision about participating in research. This LOI is often sent as a Word document, but you might find it more appropriate to include this information in an email to your participant rather than as a separate document. Be sure to save a copy of that email for future reference (and encourage the pianist to do the same).

When communicating with participants for your study, bear in mind that TCPS2 encourages you to use your discipline's norms and standards as a yardstick for conduct, and also that the REB, during review of your study's application, needs to know that your participants will be fully informed about what they are agreeing to, how their information will be used, and their rights as research participants. This is in order for the REB, and through them the Tri-Council, to be assured that your participants' consent is both **informed** and **ongoing**, as well as **entirely voluntary**.

Consent: specifics

TCPS2 Article 3.12, Chapter 3 stipulates that the consent of human participants must be documented; it does not, however, insist on written documentation, understanding that in some instances written documentation is not appropriate for all participants. Near the end of this package is a letter of information and consent (LOI/C) document checklist (see Appendix 3), which outline the kinds of information you'll need to communicate to participants before asking them for their consent, as required by TCPS2.

LOI/C documents in human research studies are generally printed, presented to participants, and hard-copy signatures are obtained; however, this information, and the informed consent of a participant, can also be provided and obtained in other, related ways, depending on what is appropriate for your discipline and/or the nature of your relationship to the participant you are recruiting.

In your REB application you will be required to specify how you plan to document participants' consent, and to explain, if you are not obtaining consent in writing, why this alternative method is appropriate to your project. For example, consent may be obtained by:

- Clicking a link on an anonymous survey which states clearly that clicking said link implies consent to continue;
- Requesting a reply to your solicitation/recruitment email, as in the example above about the pianist, that confirms the participant is comfortable and voluntarily undertakes the project on the terms you describe;
- Communicating information about project scope, data collection, and the process for withdrawing consent on an audio recording at the start of an interview, and asking for verbal consent, which is recorded on the audio;
- Attending a focus group, where the Letter of Information describes all relevant information and notes that attending the focus group session would be taken as an indication of participants' informed consent to participate in the research;
- Explaining the project's details and the terms of participation using community-specific protocols. For example, obtaining community-level consent prior to engaging in any individual-level consent-gathering processes and research activities, and/or participating in culturally

appropriate gestures of agreement (e.g., a hand shake, sharing of tobacco or sweet grass, etc.). You would be expected to explain the anticipated protocols in your REB application prior to approval (i.e., this is why community engagement is so important for developing the design of your project prior to submitting to the REB), and then, when engaging in these discussions/activities, you would be expected to document in writing (e.g., in field notes) what you said, what was done, and how those who are to participate communicated to you that they consent to the terms you have outlined. (Note that specific considerations for working with Indigenous participants are needed; be sure to consult TCPS2 Chapter 9: Research Involving the First Nations, Inuit and Métis Peoples of Canada.)

- Hosting information sessions describing the research objectives and procedures and providing space for potential participants to get to know the research team, ask any questions, and have interpreters present to facilitate these discussions. (Note: Any third parties such as interpreters are required to sign confidentiality agreements.)

As ever, bear in mind that TCPS2 makes room for, and the Non-Medical Research Ethics Board at Western supports, best practices for recruitment and consent documentation in different disciplines, study designs, and contexts.

However, whatever specific tools or processes are used for recruitment and consent and their documentation, it is the responsibility of all researchers seeking REB approval to ensure that their human participants are fully and properly informed of what they will be asked and how the information they provide will be used, that these participants actively consent after learning about and understanding this information, that they are free to withdraw their consent at any time (if possible), and they are given the opportunity to ask any questions prior to consenting.

This brings us to the end of Part One of the handbook, which was designed to help you determine when REB review is needed and to highlight some of the relevant information you will need to know to prepare for conducting research involving human participants.

Part Two of this handbook is designed to support you if you have determined that REB review IS required for your project and to help you get started. Feel free to 'stop here' and turn back to Part Two at a later time, as needed.

Remember to also check out the appendices at the end of the handbook as well for more information, tools, checklists, etc. to support you in this process.

PART TWO:

Great - you have determined that your project requires REB review! Now, you might be wondering, “where do I even start?” This second part of the handbook details just that: everything you need to know to get started, as well as what you’ll need to know and/or do to successfully engage with the REB process throughout the life cycle of your project.

Section 1: Preparing for REB Review

This section highlights the required groundwork prior to preparing your REB application.

Mandatory human research ethics training

All researchers engaging in research involving humans must complete online research ethics training. More information can be found here under [‘Mandatory Training for Human Research’](#).

Confirming Research Eligibility

You will need to confirm whether you are eligible to be the Principal Investigator (PI) on your project. At Western, this role is limited to those with research-eligible University appointments - most often, faculty members. For more information, please see the Research-Eligible Faculty Appointments password protected document on [Western Research Policies](#) webpage.

Important Note: Students and postdoctoral scholars cannot be PIs, even when the research is being conducted for their theses/dissertations or they are otherwise being considered the lead researcher. In these cases, the PI would usually be their academic faculty supervisor (see Faculty Collective Agreement Appendix E for more information on supervisory responsibilities). It is typical in these cases for students to prepare the REB application with supervision from their departmental supervisor and support from a research ethics officer; it can also provide useful experience for all involved! Note that in these cases, the PI academic faculty supervisor or other remains ultimately responsible for ensuring that the research is conducted in accordance with the approved protocol.

Determining board and level of review

It is expected that most, if not all, arts and humanities research will qualify for Non-Medical Research Ethics Board (NMREB) review (for more information on which REB you should submit to, see [here](#)).

Also, most of the projects submitted to the NMREB are low-to-minimal risk studies and thus often qualify for what is called ‘Delegated Review.’ This level of review entails typically one (or two) board member(s) with similar expertise to your area of research and/or methodology (usually someone in your faculty/department), along with an ethics officer (from the Office of Human Research Ethics), reviewing your application for completeness, ethical soundness, and logistical feasibility.

If your study involves more than minimal risks to participants, and/or participants who are considered vulnerable in the context of your research, then your project may require Full Board review. Whether your study is low-risk or high-risk, the application will be the same for you. It is determined by the Ethics Officer whether your study will require Full Board review after they receive your application. This is where a group of faculty members across campus and community representation convene to discuss higher risk research projects in accordance with TCPS2. Full Board NMREB meetings occur only once per

month, so you will need to be mindful of the [submission deadlines](#) if you think your study will require full board review.

An example of a low-risk, delegated application: you are asked to interview a noted author for a scholarly journal. The author will be speaking about their own practice for the advancement of your or others' research into their body of work. In this case, the interview would qualify as "research" because you are advancing disciplinary knowledge about the author; however, given that the author would be speaking on the record about their own work and of their own accord, risk to them is very minimal. However, it is important to note that they are still entitled to all rights afforded to any research participant.

An example of a higher-risk, but still delegated application: you are observing rehearsals at a theatre company, with permission of the director and other stakeholders, in order to discuss the process of a play's development from page to stage. You choose to interview the director and actors, with their consent. Here, even though all artists are speaking to their own practice, the actors and/or director may be in positions of vulnerability as employees, even temporary, of the theatre company; they may also be concerned with their professional reputation. In this case, REB review will ensure that you have the tools to obtain the information you require for your research while carefully protecting the artists in question from present or future economic harm.

An example of a full board application: you are interested in investigating the value of creative expression as a mode of supporting survivors of abuse heal from trauma, and you intend to develop workshops aimed at understanding the benefits of art as a psychotherapeutic intervention. Due to the potential risks associated with this research given the vulnerability of the participants and the sensitivity of the research topic, this project will require full board review to evaluate the anticipated benefits of the research compared to the risks (such as emotional triggers, confidentiality limitations, etc.), and to ensure that you and your research team are prepared to protect your participants' rights and wellbeing.

Managing timeline expectations

You are encouraged to submit your REB application at least a couple of months before you intend to begin your research involving humans to allow for review time, including any revisions and clarifications which may be needed prior to REB approval. If you are new to the process, you will want to consult with the Ethics Office before you begin your application in order to ensure that it is as complete and properly prepared as possible; this will ensure your application proceeds through the review process smoothly.

Note: You may still engage in any research activities that do *not* require REB review (e.g., literature reviews, use of publicly available information, preliminary exploratory information gathering, etc.) during this time, but recruitment and data collection for any research involving humans must only begin after REB approval has been received.

Section 2: Submitting the REB Application

Conceptualizing your project as 'research involving humans' may require you to think differently about your projects than you are used to thinking about them and seeking REB review especially for the first time - may seem especially daunting. As suggested by the range of examples provided in the above sections, every project is going to be unique and will carry its own distinct ethical challenges. It's impossible to anticipate every ethical and administrative consideration that arts and humanities

researchers will need to prepare for, but this section provides some high-level information to support you in this process.

Creating an online application via WREM

Once you determine that REB review is needed for your project and you have developed a plan for carrying out your research, you will need to submit an application to Western's REB through a secure online platform called Western Research Ethics Manager (WREM). See Appendix 5 for instructions on accessing WREM, obtaining an account, and accessing training materials.

Describing your project

It is important to consider the audience of the different components of your REB application and study documents, as this will impact the types of information and language you will want to use in these materials.

The REB application is written primarily to the REB and ethics office staff. In some instances, research compliance monitors may require access to these records as well. The writing should be professional, clear, and concise, striking a balance between academic and lay terminology so that both experts and non-experts can evaluate the ethical implications and practical components of your work.

When filling out the REB application, you will be prompted to answer several questions about your research, including your research objectives, procedures, participants, data collection tools, recruitment and consent procedures, and confidentiality and data security measures - as applicable to your specific discipline and research context.

Study recruitment and consent documents, on the other hand, are written directly to the people you will be giving them to so be sure to draft them with their background knowledge and needs in mind (as applicable). See Appendix 2 for sample recruitment, and Appendix 3 for a checklist of information expected to be communicated in consent materials.

Some of the language used in the REB application may seem foreign to arts and humanities scholars, so we have included a breakdown of several key questions in the REB application with specific tips to help you answer each question correctly and thoroughly, which will minimize the number of queries/recommendations you will receive from the REB (see Appendix 4).

Responding to REB recommendations

After you submit your project to the REB for review, you will receive feedback. Most often, the REB provides recommendations for revision which are needed before the application can be approved. Submitting your response to recommendations must be done in a specific way in order to facilitate timely review and also to provide a clear audit trail of the changes made.

The response has four components:

1. **The response letter** - All REB recommendations must be copied/pasted into a separate document, with an explicit response to each commenting on how the recommendation was implemented in the revised materials. The response letter is an opportunity for the researcher to engage in a written dialogue with the REB and provide any additional commentary that might be valuable to the review process but might not be appropriate for inclusion in the REB application/documents themselves. (Note: The response letter is not approved and does not

replace making formal changes to the REB application/documents, which must then be approved.)

2. **Revised REB application** - Make the changes requested directly in the REB application in WREM. Ensure all sections of the application are updated, as needed.
3. **Tracked documents** - Any documents requiring revision need to be submitted in tracked copies, with updated version dates in the footer, so that the REB (and any monitors, if applicable) can see exactly what changes have been made.
4. **Clean documents** - Any revised documents need to be submitted as final, clean (i.e., accepted-changes) documents for REB approval, exactly as they will be used in the research.

Researchers can always reach out to the ethics officer on the file (whose name will be at the bottom of the recommendation letter OR by using the Correspond function in WREM) for more information and/or discussion as needed.

Section 3: Post-Approval Review Requirements

Most projects receive REB approval for one year, and you remain accountable for submitting any changes, unexpected problems, and updates on the status of the project as 'sub-forms' via WREM. A table summarizing these changes is provided in Appendix 7.

Amendments

If any changes to your REB application and/or study documents are required after receiving approval, you will need to submit an amendment detailing the changes. The amendment will need to be submitted to and approved by the REB prior to implementing the changes.

Notes:

- It is understood that qualitative research often involves emergent designs/topics. As such, researchers engaging in qualitative research are encouraged to preemptively anticipate the range of research activities and circumstances they may find themselves in throughout the course of their projects and the types of directions their projects may go and describe them at least in a general way in the initial application. If an opportunity arises that they had not anticipated, then they can submit an amendment for approval of the newly anticipated opportunity moving forward.
- If the research focus shifts to such an extent that the project is no longer investigating the same research question but is instead going in a new direction outside of the original scope of the project, then it might be necessary to submit a new Initial Application for REB review.

Sometimes even very small changes to a project require ethics approval; if you are planning to make a change and do not know whether or not it is subject to amendment, just get in touch with the Ethics Office for clarification.

Reportable Events

If anything occurs during the course of your project that you were not expecting (e.g., protocol deviation, serious adverse event, participant complaint, privacy breach, etc.), this needs to be reported to the REB to determine and/or evaluate a mitigation plan.

Continuing Ethics Review

The TCPS2 requires that the REB obtain study updates on all active studies no less than once per year. If your research involving humans is going to take longer than one year, then you will need to submit a Continuing Ethics Review (CER) form via WREM *prior to the study's expiry date* detailing the status of your study. You will receive courtesy reminders regarding the upcoming expiry date, but it is recommended to track your own expiry dates and ensure you submit the information on time. Failure to do so will lead to your project being closed by the REB, and no new applications from the PI will be accepted until the required information is provided. Any activities conducted in the absence of REB approval may not be included in the analysis, dissemination, etc. of your research, and may require discussion by the full board.

Study Closure

Once you are confident that all study activities involving humans is complete, you will need to submit a Study Closure form detailing the project outcomes. It is important that the projects are closed in a timely manner.

Important Note regarding Student Research: It is important that the project is successfully closed out prior to the student leaving the institution. It is also important that all study records be securely transferred to the PI for long-term storage (as indicated in the Faculty Collective Agreement, unless justified and approved in the REB application).

Appendix 1: Checklist for Determining if REB Review is Needed

| Questions prompting for exemptions | | Answer | | | Review Outcome |
|------------------------------------|---|--------|----|--------|--|
| Q# | Does your project... | Yes | No | Unsure | |
| | Meet the definition of “research involving humans,” according to the Tri-Council Policy Statement? (see definitions and discussion in handbook Part One Section 1) | | | | <p>Yes - Continue asking Q#1-6 to see if the research activities require REB review.</p> <p>No - Exempt</p> <p><i>Unsure - Consult TCPS2 Article 2.1 and Application, and then consult with the OHRE as needed.</i></p> |
| 1. | Rely exclusively on publicly available information? | | | | <p>Yes - Exempt</p> <p>No - Continue asking #2-6.</p> <p><i>Unsure - Consult TPCS2 Article 2.2, and then consult the OHRE as needed.</i></p> |
| 2. | Rely exclusively on naturalistic observations, where there is no expectation of privacy OR manipulation/intervention in the environment? | | | | <p>Yes - Exempt</p> <p>No - Continue asking #3-6.</p> <p><i>Unsure - Consult TCPS2 Article 2.3, and then consult the OHRE as needed.</i></p> |
| 3. | Rely exclusively on the secondary use of previously collected ANONYMOUS information? <i>Note: This does not include coded or anonymized data.</i> | | | | <p>Yes - Exempt</p> <p>No - Continue asking #4-6.</p> <p><i>Unsure - Consult TCPS2 Article 2.4, and then consult the OHRE as needed.</i></p> |
| 4. | Qualify as a quality assurance, quality improvement, or program evaluation (QA/QI/PE) project being conducted for the sole purposes of internal assessment, management or | | | | <p>Yes - Exempt*</p> <p>No - Continue asking #5-6.</p> <p><i>Unsure - Consult TCPS2 Article 2.5.*</i></p> <p>*NOTE: If you require formal documentation that your project is</p> |

| | | | | | |
|--|--|--|--|--|---|
| | improvement purposes <u>and not</u> academic research? | | | | QA/QI/PE, OR if you are unsure and would like OHRE confirmation, then please submit a QA/QI/PE application form in WREM. |
| 5. | Qualify as creative practice, in which any involvement of humans is <u>not</u> academic research? (see discussion on page 3) | | | | Yes - Exempt No - Continue asking #6. <i>Unsure - Consult the OHRE for discussion.</i> |
| 6. | Involve preliminary discussions and/or community engagement that are necessary prior to the development of a research project (e.g., to determine the feasibility of research, establish partnerships, or to design a research proposal)? <i>Note: If results from this phase of research need to be included in the research data or outcomes, research ethics approval is required.</i> | | | | Yes - these preliminary, exploratory interactions are Exempt. No - No actions needed. <i>Unsure - Consult TCPS2 Articles 6.11 and 10.1.</i> |
| If you are conducting research involving humans that does not meet any of the exemption categories listed above, then you will need to submit an REB application via WesternREM. | | | | | |
| <p>Special Note for Course Instructors:</p> <p>If, as part of course requirements, students will engage in research involving humans not otherwise exempt from REB review, then a Pedagogical Application via WREM will need to be submitted detailing the student projects and how it will be ensured they will be conducted in accordance with ethical principles. See the REBs' Student Research and Pedagogical Activities guidance document available here for more info.</p> | | | | | |

Appendix 2: Recruitment Sample

Below is an example of how an informal but ethically appropriate recruitment procedure could be carried out in the context of arts and humanities research.

Note: Each of these scripts would be uploaded as separate documents, where prompted in the REB application.

Verbal script for in-person recruitment:

Hi, I'm [insert name] and I am studying music performance studies at Western University. Wow - what a great show! I'd love to learn more about your techniques for practicing and preparing for such performances. This work is part of my thesis and would entail a half hour interview at a time/date of your choice, if you're interested?

[if yes] Great! Could I get your email address to send you some more information about the research and set up a time to meet?

[collect information] Thanks so much. Looking forward to meeting with you.

[if no] No problem! Thanks again for a great performance today. Take care.

Corresponding email script if potential participant agreed to follow-up:

Hi! It was so great meeting you at your show last weekend. Thank you again for your interest in my research.

As mentioned, I am conducting research as part of my Master's thesis (under the supervision of Dr. _____), and I am hoping to understand more about the techniques and strategies used by professional musicians in preparing for their upcoming performances, including whether there might be any differences between preparing for live vs. recorded performances. I am hoping to talk with a number of performers across Ontario and engage in one-to-one interviews via Zoom. If you are comfortable, I would like to audio-record the interview as well so that I can make a transcript of our conversation for later analysis. (If you are not comfortable being recorded, I will take notes as we speak.) Only with your permission will I identify you in any reports of this research; that is, you can choose to be identifiable or anonymized in this research.

Please find attached a Letter of Information and Consent, which provides additional details about your rights as a participant and the objectives of the research. If you get a moment, please review this document prior to our interview, and let me know if you have any questions/concerns. I will obtain your verbal consent at the time of the interview.

Thanks again!

Best,

[your name]

[your affiliation]

[your supervisor's name, affiliation, and contact information]

Appendix 3: Letter of Information and Consent (LOI/C) Document Checklist

To create this document, we recommend that you consult the general NMREB Letter of Information and Consent (LOI/C) guidance document available in the WREM Help tab (under Templates) or on the Human Ethics Guidelines and Templates webpage. This guidance document will include up-to-date information you need to prepare your LOI/C.

In short, the LOI should include the following information:

- Y Study title (consistent with WREM)
- Y Western letterhead/logo in header or footer
- Y Pagination in header or footer (Page X of Y)
- Y Version date in header or footer (DD/MMM/YYYY)
- Y Information that the individual is being invited to participate in a *research* project
- Y A statement of the research purpose in plain language
- Y The identity of the researcher
- Y The identity of the funder or sponsor
- Y The expected duration of participation
- Y The expected nature of participation
- Y A description of research procedures
- Y An explanation of the participants' responsibilities
- Y A plain language description of all reasonably foreseeable risks that may arise from participation
- Y A plain language description of potential benefits (to participants and in general)
- Y An assurance that prospective participants are under no obligation to participate
- Y An assurance that prospective participants may withdraw at any time without consequence
- Y An assurance that prospective participants will be given timely information relevant to decision to continue or withdraw participation
- Y An assurance that prospective participants have the right to request withdrawal of data (if feasible) or any limitations on withdrawal
- Y Information concerning possible commercialization of research findings
- Y Information concerning real, potential, or perceived conflicts of interest
- Y Measures to be undertaken for dissemination of results, including results reported back to participants
- Y Information regarding whether participants will be identified directly or indirectly
- Y An indication of what information will be collected about participants and for what purposes
- Y An indication of who will have access to information collected about the identity of participants
- Y A statement to the effect of the following: "Delegated representatives of Western University and its Non-Medical Research Ethics Board may require access to your study-related records to monitor the conduct of the research."
- Y A description of how confidentiality of all collected data will be protected, and for how long
- Y A description of the anticipated uses of data
- Y A statement re: open access, if applicable
- Y Information indicating who may have a duty to disclose information collected and to whom such disclosures could be made
- Y Information about any payments (compensation, incentives, reimbursements)

- Y A statement to the effect of the following: “You do not waive any legal rights by consenting to this study”
- Y The identity and contact information of a qualified representative who can explain scholarly aspects of the research
- Y The identity and contact information of the OHRE (incl. long distance number: 1-844-720-9816) for any questions regarding participant rights and/or concerns about the study
- Y A statement that participants will receive a copy of the LOI/C for their records

Depending on the method of consent you are obtaining, the accompanying consent documentation should entail the following:

Basic Required Information for Written Consent Page:

- Y Consent form is on a separate, final page of the LOI document
- Y Study title, letterhead/logo, pagination, version data and investigator name, affiliation and contact information included on consent form
- Y A statement indicating the following, prior to the participant’s signature lines: “I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.”
- Y Any optional consent statements, with yes/no checkboxes, prior to the participant’s signature lines
- Y A statement indicating the following, prior to the researcher’s signature lines: “My signature means that I have explained the study to the participant named above. I have answered all questions.”
- Y Spaces for participant and person obtaining consent to print their name, sign and date
- Y Spaces for parent/legal guardian, translator, substitute decision maker, witness, etc. to print their name, sign and date, if applicable

Basic Required Information for Verbal Consent Script:

- Y Separate, final page of the LOI document
- Y An indication of what will be read to participants (e.g., full LOI? Abbreviated script with all required components)
- Y A question asking whether participants have received the LOI information, have had all questions answered, and whether they agree to participate
- Y Questions eliciting any optional consent options

Basic Required Information for Implied Consent:

- Y A statement at the end of the LOI indicating how consent will be implied (e.g., “Submitting the survey is indication of your consent to participate.”)

Appendix 4: Translating the NMREB Initial Application

Several resources are available on the [Human Ethics guidelines and templates webpage](#), which will directly assist in the completion of an REB application. Please refer to these resources as applicable.

As well, the following table highlights some key questions in the REB application to support arts and humanities scholars in completing the form.

| WREM Section/ Question | Content Requested | Tips |
|------------------------|---|--|
| Q1.1 | Submission type (initial submission or response to recommendations) | ONLY select 'Response to REB Recommendations' IF you submitted this particular REB application before and have already received specific REB feedback via WREM. This will populate another section of the application, 'Resubmission Information,' which will prompt you to submit the response letter and tracked changes copies of the revised documents. |
| Q1.2 | PI information | ONLY the research eligible study team member (faculty supervisor?) assuming responsibility for the project can be listed here. "Co-PI's" do not exist at Western (only one PI). |
| Q1.3 | Study team members, roles, and duties | <ul style="list-style-type: none"> – Western-affiliated study team members require WREM accounts in order to be searched in the directory. – If you are a student and you are creating the application, be sure to also add yourself to Q1.3 as an additional study team member. (Remember that you cannot, as a student, be a PI) – All study team members' specific duties need to be listed so that the REB knows who is doing what (incl. recruitment, interacting with participants, handling identifiable information, etc.) – Be sure to specify Department/Faculty for each study team member. |
| Q1.4 | Study team members outside of Western | <ul style="list-style-type: none"> – This could include partners at other academic institutions, artistic collaborators, community advisors, etc. – Be clear what these collaborators' roles will be, including whether they will have access to data (and if so, what type of data - identifiable? De-identified?) |

| | | |
|-------|-------------------------------|--|
| Q1.13 | Lay summary | <ul style="list-style-type: none"> – Think of this as your 3 min elevator pitch, or how you would describe your project to a non-expert relative or friend. – This information is shared across all sub-forms associated with this project so should briefly summarize the objective, procedures and expected outcomes in lay terminology. |
| Q2.1 | Rationale | <ul style="list-style-type: none"> – What does the literature say? Why is this research important? What contributions are expected from this work? |
| Q2.2 | Research questions/hypotheses | <ul style="list-style-type: none"> – What is(are) the overarching question(s)/hypotheses guiding this project? Are there sub-questions? – Note: These are not the interview questions themselves, which are collected later in the form. These are the general questions that will be answered/explored. |
| Q2.4 | Study procedures | <ul style="list-style-type: none"> – Step-by-step, all logistics need to be described. This needs to be as specific as possible without unnecessarily pigeon-holing yourself (e.g., provide ranges in expected time commitment, locations of study activities, etc.). – In theory, another person should be able to replicate these procedures by reading this section - while also taking into account the often emergent nature of creative research. See TCPS2 Chapter 10 (Qualitative Research). |
| Q2.5 | Study instruments | <ul style="list-style-type: none"> – All study materials used in data collection are needed, including interview questions/probes, surveys, stimuli provided to participants, observation recording sheets, etc. – The REB needs at minimum a representative sample of what participants will see/be exposed to in their participation. |
| Q2.6 | Use of technological tools | <ul style="list-style-type: none"> – Western-provided tools are always best (including but not limited to: Office 365, OWL, Qualtrics, Zoom). – Other third-party platforms may be used, but may require institutional review from Western’s Technology Risk Assessment (TRA) Committee. Contact them for more info if |

| | | |
|-------|-------------------------|--|
| | | <p>needed (uwo-risk@uwo.ca), or consult their website.</p> <ul style="list-style-type: none"> Information should only be stored on third party platforms for as long as needed, and then exported and securely stored on an institutional server/drive. |
| Q2.14 | Anticipated sample size | <ul style="list-style-type: none"> Sometimes this will be clear cut (e.g., if you know exactly how many people might be included as you only have specific people you want to talk to); other times, you may have no idea how many people will be included (e.g., online surveys, audience feedback, informal observations in a private setting). The expected number of people and/or the rationale for ending sample will depend entirely on the nature of the research question, the methods being employed, and the context of the research initiative. It is okay if this number is a rough estimate, and if the researchers recruit/consent more than this number when in the field. |
| Q2.15 | Participant description | <ul style="list-style-type: none"> In arts and humanities research settings, the language of ‘inclusion/exclusion criteria’ may not be entirely clear. Some projects may only involve a few specific people (e.g., the director and lead actor of a performance), so the inclusion criteria here would simply be whoever holds that specific role or knowledge/experience necessary for answering your research question. Other projects may include a wide range of people who may not have any specific role or expertise, but rather are of research interest because of some common experience (e.g., the audience of a show). Here, the inclusion criteria would be anyone who attends the show and consents to participate). Simply describe the characteristics/qualities about the person(s) being invited to participate in your research (i.e., why are they and/or their perspectives/ experiences/etc. important to answering your research question?) |

| | | |
|-----------|---|--|
| Q2.19 | Research dissemination | <ul style="list-style-type: none"> – Creative strategies are often used in arts and humanities research dissemination activities. Select all that apply, and describe them to the best of your ability (noting, of course, that some opportunities may arise that are unforeseen at the time of submitting the REB application given the emergent and creative nature of this research). |
| Q4.1 | Recruitment procedures and documents | <ul style="list-style-type: none"> – Be specific, and include all anticipated recruitment strategies. – Use of publicly available information is very common. – Snowball sampling is an appropriate method of recruitment, but it is preferred that potential participants’ names and contact information not be shared with researchers without their knowledge (unless already publicly available) - in order to respect privacy/confidentiality and also promote the voluntary nature of research. – Social media recruitment is appropriate as well, but there are specific guidelines for this. – See REB Participant Recruitment Guidelines document available here for more information. |
| Section 5 | Informed consent procedures and documents | <ul style="list-style-type: none"> – Depending on your research, you may request a waiver of consent (e.g., in the case of secondary non-identifiable information) and/or document your proposed consent procedures (e.g., for secondary use of identifiable information, or for prospective research). – Informed consent can be obtained in many ways; it is a process that involves a document and documentation. Consider when/how you will inform participants and when/how you will document consent. |
| Section 7 | Participant confidentiality | <ul style="list-style-type: none"> – When directly interacting with participants, there is necessarily some level of directly identifiable information necessary to carry out the research. – If participants will be directly identified in the study records and dissemination, then this |

| | | |
|--|--|---|
| | | <p>needs to be justified why it is appropriate in this case and participants need to provide fully informed consent to this identification.</p> <ul style="list-style-type: none">– If participants are given the option to be de-identified, then the default should be that all participants are de-identified and assigned a unique ID code with a master list to allow the researcher to link the data if needed. Anyone who opts into being identified, then can be re-linked upon dissemination. This also respects participants' right to change their mind, and ensures their confidentiality will be protected in the event of a privacy breach.– If data are collected anonymously, then there will be no way to facilitate data withdrawal. |
|--|--|---|

Appendix 5: WREM Resources

Western Research Ethics Manager (WREM)

Log in: <https://applywesternrem.uwo.ca/>

New User?

- Register for an account using your UWO email address.
- Your account will be activated in approximately 24 hours.

WREM Training:

Available on Western's Human Research Ethics [Workshops and Seminars](#) webpage

- User Guides and Training Manuals (*note: also available in WREM Help tab > Help page*)
- Pre-scheduled online webinar sessions (WREM 101) - registration required.
- WREM Quick Facts document

A few general tips:

- Pay attention to the Actions buttons.
 - Clicking the Next, Previous & Navigate buttons will move you through the application AND also save any changes made to the page.
 - If you are on any single page for an extended period of time, be sure to Save.
 - The Correspond button will send a notification directly to the Ethics Office staff if you have questions/concerns.
- Read every REB application question carefully and respond fully.
- Click the little blue I icons to the right of some questions which provide 'help text' - additional information about the REB application questions to assist you in answering the questions.
- Refer to the guidance documents and templates available in the WREM Help tab (under Templates) as needed – which will provide general supplementary resources to the information provided in this handbook.

Appendix 6: New Projects - WREM Applications

WREM Application Forms (i.e., Create Project)

| | |
|-----------------------------|--|
| Initial HSREB or NMREB Form | This is the main application form to be used for all projects requiring Research Ethics Board (REB) review. https://www.uwo.ca/research/ethics/human/Resources/which_reb.html |
| Multijurisdictional Form | This form is used to help Western researchers determine if Western's REB oversight is required for their role in collaborative, multi-jurisdictional research projects. See Multijurisdictional guidance document. |
| QA/QI/PE Form | To confirm whether a project is considered Quality Assurance (QA), Quality Improvement (QI) or Program Evaluation (PE), and therefore does not require REB oversight, submit this form. See QA/QI/PE guidance document to help you determine if your project is research or not. |
| Pedagogical Form | Pedagogical research projects being carried out within the context of a course require the instructor to submit this form. See Student Research and Pedagogical Activities guidance document for more information. |
| Cadaveric sub-REB Form | All research involving human biological material obtained through Western's body bequeathal program must be submitted through this form. |

Appendix 7: Post-Approval Events (WREM Sub-Forms)

Required Post-Approval Submissions (i.e., Action: “Create Sub-Form” in WREM)

| | |
|--------------------------------|--|
| Amendment | <ul style="list-style-type: none">• Modifications to the approved application and/or study documents.• Amendments must be approved prior to implementation. |
| Reportable Events | <ul style="list-style-type: none">• Protocol Violation/Deviation = unapproved study activities• Serious Adverse Event = harmful outcome to study participant• FYI = minor updates to REB• Data Safety Monitoring Board/Committee (DSMB/C) reports• Participant complaints/privacy breaches*contact REB prior to submitting reportable event in WREM |
| Continuing Ethics Review (CER) | <ul style="list-style-type: none">• Annual update required for studies extending beyond one year.• Receipt of CER approval notice required for study continuation. |
| Study Closure | <ul style="list-style-type: none">• End of study report required when there is no further participant involvement, and all data collection, clarification and transfer is complete (including access to participants’ medical record): |

Appendix 8: Relevant Institutional Policies

Western's Manual of Administrative Policies and Procedures - [Research](#)

MAPP 7.0 - Academic Integrity in Research Activities

MAPP 7.14 - Research Involving Human Participants

Appendix 9: External Resources

Several other post-secondary institutions have also tackled these issues and have developed resources to support their faculty, students and staff navigate research ethics requirements in their arts and humanities-related contexts. See below for these external resources as supplementary tools.

Emily Carr University of Art and Design:

Risk and Review tool <https://www.connect.ecuad.ca/research/reb/resources>

University of Victoria:

Research Activities that are exempt from human ethics review and research activities that require ethics review

https://www.uvic.ca/research/assets/docs/Ethics/research_ethics_review_exemptions_and_requirements.pdf

Responsible Conduct of Research Creation (RCRC) Toolkit:

<https://papyrus.bib.umontreal.ca/xmlui/handle/1866/20924>

Guidelines for Visual Research Methods

<http://vrc.org.au/guidelines-for-ethical-visual-research-methods>

Guidelines for Oral History Methodologies

<https://www.baylor.edu/oralhistory/index.php?id=931324>

Research Ethics Scholarly Posters

<https://papyrus.bib.umontreal.ca/xmlui/bitstream/handle/1866/20005/Lit%20Poster-17.pdf?sequence=1&isAllowed=y>

https://papyrus.bib.umontreal.ca/xmlui/bitstream/handle/1866/22116/RCRCToolkit_WCRI_Poster_2019.pdf?sequence=1&isAllowed=y

Research Ethics Blogs

<http://thesiswhisperer.com/2012/06/26/human-ethics-applications-with-a-minimum-of-pain-part-one/>

<http://thesiswhisperer.com/2012/09/19/human-ethics-applications-with-a-minimum-of-pain-2/>

Appendix 10: References

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018.

Government of Canada, 2016. Retrieved from https://www.sshrc-crsh.gc.ca/funding-financement/apply-demande/background-renseignements/preparing_research_creation_application_idg-preparer_l_application_recherche-creation_sds-eng.aspx on Jan 5, 2022.

Government of Canada, 2021. Retrieved from https://ethics.gc.ca/eng/policy-politique_interpretations_scope-portee.html on Jan 5, 2022.