*This guide is for researchers to use in developing their study information letter and contains language applicable to most studies. Please read through and make the appropriate changes to ensure the information applies to your study. Instructions to the researchers are written in* ***[square brackets in bold italics]*** *and should be deleted. Instructions that are in* ***[square brackets, bold italics, and are blue]*** *need to be replaced with details specific to the study and changed to* black, un-bolded, un-italicized*, and removed from square brackets before uploading the material to the research ethics application. Letters are typically placed on University of Waterloo letterhead.*

Information-Consent Letter Guide

**[*Use Research Group, Department, and/or University of Waterloo letterhead*]**

**Study Title**: ***[Insert title]***

**Principal Investigator/Faculty Supervisor**: ***[Include affiliation (e.g., University of Waterloo plus Department, Faculty, Institute), telephone number and Waterloo email address. If an international study, include “Canada” as well.]***

**Student Investigator (if applicable)**: ***[Include affiliation (e.g., University of Waterloo plus Department, Faculty, Institute), Waterloo email address. For privacy reasons, do not include personal cell phone numbers for Student Investigators.]***

To help you make an informed decision regarding your participation, this letter will explain what the study is about, the possible risks and benefits, and your rights as a research participant. If you do not understand something in the letter, please ask one of the investigators before agreeing to participate in the study. ***[In person studies add:*** You will be given a copy of this information-consent letter if you choose to participate in the study for your records.**]** ***[Online studies add:*** You may wish to save a copy of this letter for your records**]**.

**Invitation to participation/What is the study about?**

You are invited to participate in a research study about

* Indicate the purpose and objective(s) of the study in a clear statement using language the participant population will understand.
* Describe why the research is being conducted/why this research is important (e.g., “This is important because…” or “Past research has shown…”).
* For student research, include the level of research project (i.e., for a course project/thesis/dissertation, etc.)
* Indicate if the research is a pilot study

**Additional Guidance**

* The reading level of this section, and the letter should be appropriate to the participant population. A grade five reading level is recommended.
* Be sure to use lay language when explaining the purpose and rationale of the study, and throughout the letter. If you are recruiting from the public or general student population, then jargon, terms, and language that are specific to the discipline should be avoided, so a non-specialist and people unfamiliar with the discipline can understand.
* For some participant populations (e.g., people with low vision) the font size of the letter should be increased.
* [See Using Plain Language in Participant Materials](https://uwaterloo.ca/research/using-plain-language-participant-materials)

**What does participation involve?**

**“**Participation in the study will consist of … in which you will be asked to …”

* Outline number of sessions and length of time for each session.
* Describe tasks/procedures the participant will be asked to do during the study in the order the participant will experience them (i.e., sequentially).
* Outline when sessions will be scheduled including location and time.
* If the study is conducted using online data collection methods (e.g., Survey Monkey, Qualtrics, MS Teams, Zoom, Skype) this needs to be stated along with University of Waterloo practices that maintain participant privacy, and the limits to privacy (See below and [Language for online data collection methods](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/application-process/samples-and-other-supporting-materials/information-consent-samples/information-consent-letters-and-forms#patriot%20act)).

**Additional Guidance:**

* This section should include a detailed description of the study (e.g., order of procedures, methodology, time commitment, random assignment of groups if applicable, etc.).
* If the study contains multiple sessions or procedures, consider using a numbered list or bullet points for clarity. If the study procedures/groupings and schedule are complex, consider including a flow-chart.
* If the study involves a questionnaire(s), focus group(s), interview(s), etc., indicate what kind of questions participants will be asked.
* Indicate if any expenses may be incurred and/or reimbursed
* If the study involves a **group format**, the limits to confidentiality should be explained and the following statement included, *“Given the group format of this session we will ask you to keep in confidence information that identifies or could potentially identify a participant and/or their comments.”*
* For participant groups with**limited internet access or in situations where the** researchers want to offer an **alternative to online participation** include: *"If you prefer to not participate using this online method, please contact one of the researchers so you can participate using an alternative method such as a paper-based questionnaire or telephone call. The alternate method may decrease anonymity, but confidentiality will be maintained."*

For any data collection using **online surveys/questionnaires, Skype/MS Teams/Zoom platforms, or other online data collection methods** the following language (web security statements) may need to be included in the information letter:

***[If using a University of Waterloo supported platform such as Qualtrics, Microsoft Teams, or Zoom, please include the following statement]:*** You will be participating in a study that uses ***[insert name of platform]***. ***[insert name of platform]*** has implemented technical, administrative, and physical safeguards to protect the information from loss, misuse, and unauthorized access, disclosure, alteration, or destruction. However, no internet transmission is ever fully secure or error free.

***[If IP tracking is turned off, include the following statement]:***Please Note: We do not collect or use internet protocol (IP) addresses or other information which could link your participation to your computer or electronic device.

***[If IP tracking turned on, include the following statement]:***Qualtrics temporarily collects your computer IP address to avoid duplicate responses in the dataset but will not collect information that could identify you personally.

***[If using a non-university supported platform, please contact IST to confirm security and draft an appropriate statement].***

**Who may participate in the study?**

**“**The study will involve up to … and to participate in the study you need to be ….” (e.g., be at least 18 years of age, not have a certain health condition, etc.)

* This section should include all relevant inclusion/exclusion criteria and clearly define any academic terms in lay language.
* Outline the expected number of participants if applicable

**Is participation in the study voluntary?**

“Your participation in this study is voluntary. You may decide to leave the study at any time by…”(e.g., “communicating this to the researcher” or for online studies by “not submitting your responses.)”

* For interviews/questionnaires: “You may decline responding to any question(s) you prefer not to answer (e.g., by leaving them blank, or by skipping the question)”.
* Withdrawal from the study after the study session: “You can request your data be removed from the study up until ***[insert date]*** as it is not possible to withdraw your data once papers and publications have been submitted to publishers” or “It is not possible to remove your data from the study once collected because … (e.g., data is anonymous, all identifying information is removed from the data immediately)”.

**Additional Guidance**

* Depending on the type of data being collected (e.g., anonymous, electronic, audio, etc.) different language may be needed to outline when it would be possible for a participant to withdraw their data. For language suggestions please see: [Language for stating data retention periods in an information consent letter.](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/pre-submission-and-training/human-research-guidelines-policies-and-resources/guideline-data-retention-and-how-long-researchers-should/language-stating-data-retention-periods-information-consent)

**Will I receive anything for participating in the study?**

“You will not receive anything for your participation in the study …” or “In appreciation of your time, you will receive …”. “To thank you for your time, you will receive …”. “You will be reimbursed for parking/travel/childcare expenses ...”

* If the study has multiple sessions indicate the monetary remuneration for study participation per session as well as whether the remuneration will be pro-rated for partial completion of the study and explain how the pro-rating will be calculated.
* For studies that are not pro-rated (i.e., the participant will receive remuneration no matter at what point in the study they decide to withdraw) provide information on how a participant may choose to withdraw from the study, but still receive their remuneration/incentive (e.g., by clicking through to the end of the survey).
* Include the appropriate University of Waterloo finance statement for cash or near-cash remuneration (e.g., gift card), refer to [Taxable statement for study remuneration](https://uwaterloo.ca/finance-resources/expenses/guidelines-expenses/remuneration-research-participants) below.

***[Cash or near-cash with value less than $300]****:* "The amount received is taxable. It is your responsibility to report this amount for income tax purposes."

***[Value of $300 or more]:***"The amount received is taxable. You will be asked to sign a release of personal information form for purposes of remuneration and for issuing a tax slip."

* This statement is not required for reimbursement payments (e.g., parking or bus/taxi fare).

**Additional Guidance**

* If using a draw, refer to [Language for the information letter when using a draw](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/application-process/samples-and-other-supporting-materials/information-consent-samples/information-consent-letters-and-forms#remuneration) for statements to use.
* For more information on remuneration to research participants see [Remuneration to Research Participants](https://uwaterloo.ca/finance-resources/expenses/guidelines-expenses/remuneration-research-participants).

**What are the possible benefits of the study?**

**“**Participation in the study may benefit you in the following way(s) …”, “Participation in this study may not provide any personal benefit to you …”, “The study will benefit the academic community/society in the following way(s) …”.

* A scientific or societal benefit should be provided.
* Include a statement indicating who or what groups will receive the study report/findings/publication.

**Additional Guidance**

* It is important to mention the absence of direct personal benefit when this is the case.
* The opportunity to participate in research or learn about study procedures is generally not considered a personal benefit to participants.

**What are the risks associated with the study?**

* “There is potential for…” or “There is always the risk of…” or “The *[procedure]* may cause you to feel…”. “We will attempt to minimize this risk by…”.
* Describe any potential risks associated with participation in the study (e.g., emotional, psychological, physical, social, economic, or other).
* Indicate the safeguards in place to mitigate the risks.
* If there are no anticipated risks state: “There are no known or anticipated risks associated with participation in this study”.

**Will my identity be known?**

“The research team will know which data is from your participation” or “The research team and the other participants in the focus group will know what you said” or “Your participation in this study, and the data collected, is anonymous”.

* *Anonymous information* as classified by the TCPS2 in [Chapter 5](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html) is when “the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of
individuals is low or very low”
* When choosing the phrasing, be aware of directly and indirectly identifying information, also described in Chapter 5, that may be collected
* In some studies, participants may want their identities/contributions to be known (e.g., public figure). For studies where this may be the case, this option should be provided in the information letter and the consent form should provide a provision (yes/no) for this.

**Additional Guidance**

* Anonymous data collection does not apply to all studies. “Anonymous” only applies in some studies, such as certain types of online questionnaires, but **not** in studies where the researcher meets with the participant or where the participant is asked for their name or other identifying information (e.g., phone number, email address). In most instances, only confidentiality of data can be promised to participants.
* Recruitment of participants using the SONA system in Psychology is confidential, not anonymous.

**Will my information be kept confidential?**

“Your identity will be kept confidential by…” (e.g., assigning an ID code so that individual names are not associated with the data). “All information collected from participants will be grouped together (aggregated) ...”

* “Individual results will not be shared” *(if this is the case).* “Only the research team will have access to study data.”
* If researchers plan on sharing or publishing de-identified data, then researchers cannot say the data is confidential. It is the participant’s identity and the association between that identity and the research data that is confidential. “The dataset without identifiers may be shared publicly. Your identity will be confidential.”
* “Your information will be securely stored” (e.g., in a locked research office, at the study site, encrypted, in a password protected file, etc.).
* “Any data that will be stored on a mobile device will be encrypted…”
* “Research data will be retained for minimum of ***[X]***years.”
* Describe any measures taken to keep study data confidential (e.g., encryption) and indicate who will have access to it (e.g., only members of the research team).
* If you are asking for consent to deposit data into a repository, provide details on the repository (name, links to governance or data sharing policies), who will be able to access the data, what data will be shared, withdrawal of data after deposit, and benefits of sharing data in this way. If there are specific requirements to access data (e.g., ethics review, data sharing agreements) or limitations (no commercial use) these can also be described.

**Additional Guidance**

* See [Guideline on ‘data retention and how long researchers should keep their study data’](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/pre-submission-and-training/human-research-guidelines-policies-and-resources/guideline-retention-study-information-and-data)
* Data stored at the University of Waterloo should be secured in accordance with University of Waterloo policies outlined at [Information Security Services.](https://uwaterloo.ca/information-systems-technology/about/organizational-structure/information-security-services)

**Future Data Use**

* If you are asking for broad consent to store and use data in future projects participants must be provided with enough information to make an informed choice about this decision. Topics to be covered are described in [Article 3.13 of TCPS 2](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html)
* If you would like to deposit data into a repository, provide a general description of the repository and its governance. Consider including a link where people can read more.
* If there are plans to retain the data in lab for future projects describe this.

Some potential options for phrases that can be included when writing this section:

***[Example phrases for reasons why data may be stored or shared]:***

* + “Letting us share your data is voluntary. You can still be in the study if you do not agree to this.”
	+ “Sharing data allows other researchers to easily verify results.”
	+ “Sharing data helps to avoid duplicating research efforts and allows existing data to be reused to answer new research questions.”

***[Example phrases for confidentiality and security of data being stored, shared, and/or used in the future]:***

* + “The data we share will not have you name on it, so people will not know your name or which data is yours. We will also not share any other information that we think might help people who know you guess which data are yours.”
	+ “Steps have been taken to make sure the risk of identifying you is minimized. However, new technologies may evolve that introduce new risks to privacy”
	+ “Your data may be accessed by researchers who are not subject to the ethics guidelines that we follow”
	+ “Your data may be used for commercial purposes. If this is done, you will not receive any financial benefit from this.”
	+ “Your data will only be use in other REB approved research projects.”
	+ “Access to data will require a detailed plan for the use of the data.”
	+ “If you would like your data removed, please contact…”
	+ “Once your data is deposited, you will not be recontacted about reuse of your data in future research projects. It will not be possible to remove your data once it has been shared because we will have no way of knowing which data is yours.”

**Who is sponsoring/funding this study?**

“This study is funded/sponsored by ...”

* If the study is funded, indicate who the sponsor(s) of the study is.
* If the study is not funded either state that the study is not funded or do not include this heading in your information letter.

**Has the study received ethics clearance?**

“This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB ***[####][Replace #### with the file number that is listed at the top of your ethics application]***. If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or reb@uwaterloo.ca.”

* The wording should be inserted exactly as it is presented above.

**Who should I contact if I have questions regarding my participation in the study?**

“If you have any questions regarding this study or would like additional information to assist you in reaching a decision about participation, please contact ***[researcher name]*** at ***[phone number]*** or by email at ***[University of Waterloo email address]***”.

* Optional: “You can also contact any member of the research team listed on the first page.”

**Additional Guidance**

* Ensure it is clear that the researchers are to be contacted for all general questions regarding the study. The ethics clearance information (and the Research Ethics contact information) should be in a separate section from the researcher’s contact information to avoid people contacting the Research Ethics Office for general study information.

**What if the study procedure(s)/topic causes me distress/concern?** (**Optional Section for studies that involve sensitive questions/vulnerable population)**

* If the study takes place at the University of Waterloo, provide a contact number for University of Waterloo services (e.g., Counseling Services, Health Services, etc.).
* If the study is affiliated with a specific centre/organization that is equipped to counsel participants regarding any distress/are experts in the subject matter, provide a contact number for this centre/organization.
* If appropriate, researchers can provide a list of resources located in the community where the study is being conducted. For example, contact information for the local hospital/walk-in clinic, local counselling services (KW Counselling Services, etc.).

***[Please check that all relevant study details are included, changes are made to the document to accurately describe the study and procedures, and delete the instructional text printed in bold italics before submitting to the Office of Research Ethics for review.]***

**Guide to Creating a Consent Form**

*This guide is for researchers to use in developing their study consent form and contains language applicable to most studies. Please read through and make the appropriate changes to ensure the information applies to your study. Instructions to the researchers are written in* ***[square brackets in bold italics]*** *and should be deleted. Instructions that are in* ***[square brackets, bold italics, and are blue]*** *need to be replaced with details specific to the study and changed to* black, un-bolded, un-italicized*, and removed from square brackets before uploading the material to the research ethics application. Letters are typically placed on University of Waterloo letterhead.*

# ***[Please read through and only add consent options that are applicable to your study]***

# **Consent Form**

By providing your consent, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

* The above statement is necessary on consent forms

**Study Title: *[insert title]***

I have read the information presented in the information letter about a study conducted by ***[insert name of principal investigator/faculty supervisor and name of student investigator if applicable; also include your department/school/institute name and University of Waterloo; if the study is international, please add “Canada” when mentioning the University of Waterloo]****.* I have had the opportunity to ask questions related to the study and have received satisfactory answers to my questions and any additional details.

I was informed that participation in the study is voluntary and that I can withdraw this consent, and any limitations to this withdrawal, by informing the researcher.

“This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Board (REB ***[####][Replace #### with the file number that is listed at the top of your ethics application]***. If you have questions for the Board, contact the Office of Research Ethics, toll-free at 1-833-643-2379 (Canada and USA), 1-519-888-4440, or reb@uwaterloo.ca.”

For all other questions contact ***[insert researcher contact information]***.

I agree of my own free will to participate in this study.

Participant name: \_\_\_\_\_\_\_\_\_\_

Participant signature: \_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

**Additional guidance:**

* The signature section above is for written consent forms. For Verbal Consent please include a verbal consent log and a checklist for the researchers to check off the consent options that participants agree to or not. For Online consent, please consider using radio yes/no buttons for each consent option. See our samples for further example.
* Some consent options must be agreed upon to move forward with the overall study, whereas other options may be agreed upon but are not necessary to participate. Please consider this when choosing the language to ensure your study objectives are met (i.e., I’m aware/I agree/I give permission, etc.) and clearly indicate which consent option would be required to participate in the study.

***[Other available consent options: These are meant to be examples and are not an exhaustive list of procedures/practices for which you may wish to request express consent. Include the following statements if relevant.]***

***[If the dataset may be shared in a repository participants should be asked if they agree to this, please refer to additional guidance in the Guide to Creating an Information letter.]***

* “I agree that my data can be shared in an online repository as described in the information letter.  Yes  No”
* “Do you agree to share the information that you provide from this study in an online public repository/database as described in the information letter? The data will be de-identified and will not include names or other identifying information.  Yes  No”

***[For use in future studies, please see the Guide to Creating an Information Letter for information about what details to include]:***

* “I agree to allowing my study data to be used for future purposes as described in the information letter.  Yes  No”

***[Audio and video recording for transcription/analysis purposes only]:***

* “I agree to my ***[interview/study session]*** being audio recorded for accurate transcription and analysis.  Yes  No”
* “I agree to my study session being video recorded for the purpose of ***[insert purpose/reasons e.g., tracking my movement for analyses purposes.]***  Yes  No”

***[Audio/video clips, images for public use such as presentations, teaching, publications, etc.]:***

* “I agree to allow audio/video clips, digital images, or photographs in which I appear to be used in teaching, scientific presentations and/or publications with the understanding that I will not be identified by name. ***[If the clip or image includes a participant’s face or other identifying features, indicate if this will be blurred/obscured].***  Yes  No”

***[Use of anonymous quotations]:***

* *“*I agree to the use of anonymous quotations in any thesis or publication that comes from this research.  Yes  No*”*

***[Use of a pseudonym for quotations]***

* “Do you agree to the use of quotations in any paper or publication resulting from this study with the understanding that a pseudonym will be used in place of your real name (e.g., Jane Doe)?  Yes  No”

***[Use of attributed quotations]:***

* *“*I agree to the use of direct quotations attributed to me only with my review and approval.  Yes  No*”*

***[For studies which may lead to the discovery of*** [***incidental/secondary findings***](https://uwaterloo.ca/research/office-research-ethics/research-human-participants/report-problems#IF)***:]***

One of the assessments we use in this study is the [insert name of procedure]. This is an assessment that has been found to be useful to detect [insert condition/abnormality]. Although it is not our intent to examine participants for [insert condition/abnormality] and we are in no way qualified to make any conclusions about your health status, we do want to give you an opportunity to be informed of your result if you wish. It is your decision if you would like to be notified if we find that your results are below/above what is considered typical for a person your age. If you choose to be notified of your result, we encourage you to share this information with your physician/primary health care provider to discuss whether you should undergo further testing or examinations.

Do you wish to be notified if we find your result is below/above what is considered typical?

 I wish to be notified.