Information-Consent Letter Guide

This guide provides: (a) suggestions for headings and lead-ins for each section of your letter, (b) bullet points that indicate the key elements of information that each section of the letter should provide, and (c) additional guidance for some sections located in the text boxes.

(to be printed on UW letterhead, see E-letterhead and MS Word Template)

Title of the study: Insert title

Principal Investigator/Faculty Supervisor: Include affiliation (e.g., University of Waterloo plus Department, Faculty, Institute), telephone number and 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), telephone number and email address.

"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 prior to consenting to the study. You will be provided with a copy of the information and consent form if you choose to participate in the study."

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 that the participant population will understand.
- Include the rationale for the study or a statement about why the research is being conducted (e.g., "This is important as…" or "Past research has shown…").
- For student research, include the level of research project (i.e., for a course project/thesis/pilot study, etc.).

Additional Guidance

- 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 general public or general student population, then discipline specific terms and jargon should be avoided, so a non-specialist can understand.
- The reading level of this section, and the letter as a whole, should be appropriate to the participant population. A grade five reading level is recommended for the general public.
- For some participant populations (e.g., elderly, people with low vision) the font size of the letter should be increased.

***This sample 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.

I. Your responsibilities as a participant

What does participation involve?

"Participation in the study will consist of … in which you will be asked to …"

- Outline # of sessions and length of time for each session
- Describe tasks/procedure 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, Skype) this needs to be stated along with the limits to privacy and uWaterloo practices that help to ensure participant confidentiality, found at- Language for online data collection methods.
- 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 his/her comments."

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 will be incurred *(typically this would relate to a clinical trial).*

Who may participate in the study?

"The study will involve up to … and in order to participate in the study you must 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.
- OPTIONAL: Outline the expected number of participants (*this is mandatory for clinical studies*).

II. Your rights as a participant

Is participation in the study voluntary?

"Your participation in this study is voluntary." "You may decide to leave the study at any time by…" either "communicating this to the researcher" or for online studies by "not submitting your responses."

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- For interviews/surveys: "You may decline to answer any question(s) you prefer not to answer (e.g., by leaving them blank, or by requesting to skip the question)".
- Withdrawal from the study after the study session: "You can request your data be removed from the study up until [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 used concerning when a participant can withdraw their data from a study. For language suggestions please see- Language for stating data retention periods in an information consent letter.

Will I receive anything for participating in the study?

"You will not receive payment for your participation in the study …" or "In appreciation of your time, you will receive …". "To thank you for your time, you will receive a total of …". "You will be reimbursed for parking/travel/child care expenses …"

- If the study has multiple sessions indicate the remuneration (i.e., 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 what point of the study they decide to withdraw) provide information on how a participant may choose to withdraw from a study, but still receive their remuneration/incentive (e.g., by clicking through to the end of the survey").
- Include the appropriate uWaterloo finance statement for cash or near-cash (e.g., gift card) remuneration, refer to Taxable statement for study remuneration. This statement is not required for reimbursement payments (e.g. covering parking or travel).

Additional Guidance

- If using a draw, refer to Language for the information letter when using a draw for statements to use.
- For more information on remuneration to research participants see Remuneration to Research Participants.

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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 and/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 indicate 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".

- Indicate if a participant's involvement in the study will be anonymous*. Anonymous* means the data collected will not have any identifiers associated with it and the researchers do not know the identity of those who participated.
- 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.

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Additional Guidance

- Anonymous data collection does not apply to all studies. "Anonymous" only applies in some studies, (such as certain types of online surveys) but **not** in studies where the researcher meets with the participant face-to-face 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?

"The information you share 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 may provide the dataset to publishers or in open access repositories then researchers cannot say that 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, on a password protected computer).
- "Any data that will be stored on a mobile device (e.g., laptop, tablet, etc.) will be encrypted…"
- "Research data will be retained for minimum of X years at which time it will be ... (e.g., confidentially shredded, destroyed)."
- Describe any measures taken to keep study data confidential (e.g., encryption) and indicate who will have access to it.

Additional Guidance

- See Guideline on 'how long researchers should keep their study data' at Guideline on Data Retention.
- Data stored at the University of Waterloo should be secured in accordance with University of Waterloo policies outlined at Information Security Services

III. Questions, comments, or concerns

Who is sponsoring/funding this study?

"This study is funded/sponsored by ..."

***This sample 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.

- 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.

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Has the study received ethics clearance?

"This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE#XXXXX - insert your ORE file # here). If you have questions for the Committee contact the Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore- ceo@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 (email address)".

- Optional: "You can also contact any member of the research team listed on the first page of the consent form".

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 Chief Ethics Officer's contact information) should be in a separate section from the researcher's contact information to avoid people calling the 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 uWaterloo, provide a contact number for uWaterloo 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.).

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***This sample is for researchers to use in developing their study consent forms. 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.

Title of the study:

I have read the information presented in the information letter about a study conducted by (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"). 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 by informing the researcher.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE#XXXXX - insert your ORE file # here). If you have questions for the Committee contact the Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

For all other questions contact [insert researcher's contact information].

Instructions: *Some consent options must be agreed upon in order to move forward with the overall study, whereas other options may be agreed upon but are not necessary in order to participate in the overall study. Please consider this when choosing the language to incorporate into your study's consent form to ensure that your study objectives are met (i.e., I'm aware/I agree/I give permission, etc.).*

Other consent options available (these are meant to be examples and are not an exhaustive list of procedures/practices for which you may wish to request express consent):

Audio and video recording for transcription/analysis purposes only:	☐ I agree to my interview being audio recorded to ensure accurate transcription and analysis. ☐ I agree to my study session being video recorded for the purpose of tracking my movement for analyses purposes.
Audio/video clips, images for public use:	☐ 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.*
Use of anonymous quotations:	☐ I agree to the use of anonymous quotations in any thesis or publication that comes from this research.
Use of attributed quotations:	☐ I agree to the use of direct quotations attributed to me only with my review and approval.

***This sample is for researchers to use in developing their study consent forms. Please read through and only add consent options that are applicable to your study.

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

Participant's name: _____ Date:_____

Participant's signature: _____ Date:_____

Researcher's/Witness' signature_____ Date:_____

[The signature section above is for written consent forms. For online consent forms, or verbal consent, the formatting would need to be adjusted.]

***This sample is for researchers to use if their study may uncover incidental/secondary findings. Please revise so that the information applies 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.

Title of the study:

I have read the information presented in the information letter about a study conducted by (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"). 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 by informing the researcher.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE#XXXXX - insert your ORE file # here). If you have questions for the Committee contact the Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

For all other questions contact [insert researcher's contact information].

[**For studies which may lead to the discovery of incidental/secondary findings:**]

One of the assessments we use in this study is the (name of procedure). The (name of procedure) is an assessment that has been found to be useful to detect (condition/abnormality). Although it is not our intent to examine participants for (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 to more accurately measure your (name of physiological result).

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

I do wish to be notified.
I do not wish to be notified.

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

Participant's name: _____ Date:_____

Participant's signature: _____ Date:_____

Participant's contact information: _____

***This sample is for researchers to use if their study may uncover incidental/secondary findings. Please revise so that the information applies to your study.

Researcher's/Witness' signature_____ Date:_____