

Guidance Document	Guidance for Non-Clinical Research - Letter of Information and Consent
Effective Review	Delegated & Full Board
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Legend
<p>Blue text: Guidance and/or instructions</p> <p>Black text: Suggested wording and/or example</p> <p>Red text: Language that should not be included</p>

This guidance document is not intended to be used as the template for the Letter of Information and Consent (LOI/C). It is here to help provide guidance on what should be included in the LOI/C. The template is a separate document and can be found on our website.

When writing the letter of information and consent, please remember:

1. Use plain (lay, Grade 8) language that is easy for someone not trained in your field of work to understand.
2. Remove unnecessary repetition throughout the form; if technical words are used a simple definition in lay terms should be included beside the terminology in brackets.
3. Use the “second person” voice – e.g., “You will be asked to...”
4. Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended).
5. Define all acronyms and abbreviations when they first appear.
6. The participant must be provided with a copy of the letter of information and consent form and this should be stated.
 - E.g., “This letter is for you to keep” OR “You will be given a copy of this Letter of Information once it has been signed.”
7. The only identifiers accepted on the consent form are the participant’s name and initials (initials are not required).
8. Use the term “participant” instead of “subject” in all instances to emphasize the voluntary nature of participation.
9. All letters of information and consent forms should be printed on institutional letterhead.
http://communications.uwo.ca/comms/western_brand/vis_toolkit/templates.html
10. PROOFREAD before submitting to the REB.
11. Keep the footer simple and short; it should only include the version date (dd/mm/yyyy) and pagination (“Page x of y”) on every page.
12. Do not state “This study has been approved by the research ethics board...” as this may appear to offer a guarantee of safety.

For studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) include this summary of information as required by the US federal regulations. This summary should contain only the information that is most likely to assist a prospective participant in understanding the reason for or against participating in the research, as outlined below. Some items included in the summary section may be repeated in the subsequent consent sections if necessary, to ensure the subsequent sections make sense or if the information is core to informed consent (e.g., risk of death), otherwise duplication should be avoided.

Summary of Informed Consent Form

Study Title: *insert study title as written on the protocol*

Below is a summary of information about the study. There is more information in the document (called an “informed consent form” that follows this summary. Please read the informed consent form. The research team will also talk to you about the study and you can ask any questions you may have.

Participation in research is voluntary. It is your choice whether you take part in this study.

STUDY PURPOSE

The purpose of this study is *provide a brief description of the primary reason why the research is being conducted, no more than 2-3 sentences.*

DURATION

It is expected that study participation will last *provide expected duration.* Participants will be followed for *define period of time.*

STUDY PROCEDURES

Briefly describe and highlight key study procedures and, if applicable, outline procedures that may be lengthy/burdensome to participants

This study is looking at describe purpose. Participants will also briefly describe key procedures e.g., study visits every X weeks during which the researchers will do some tests. If applicable: You will be asked to do describe lengthy or burdensome procedures which may take specify time extra time.

RISKS.

Describe the most important risks. Consider those most probable and/or highest magnitude of harm. Key information should not include the full list of risks.

Participation in this study may involve risks to you. These risks are described in detail in the informed consent form.

Include the risks participants are most likely to experience. This should not include the entire ‘very likely’ or ‘likely’ category from the main consent. Researchers must review the risks and identify those that are most likely.

The risks you are most likely to experience are:

- *Specify risk in lay language with expected frequency*

If applicable, include any serious risks. For the purposes of this summary, serious risks are considered those that may result in death, hospitalization, or are permanent.

The most serious risks are:

- *Specify risk in lay language with expected frequency*

BENEFITS.

Insert direct benefit, or state if there is no direct benefit. If direct benefit to participant is unknown but there is a greater benefit to society, include for example:

We do not know if you benefit from participation in this study but researchers hope that this study will fulfil its purpose and benefit others in future.

ALTERNATIVES.

You do not have to participate in this study to receive medical care.

Project Title

Enter the full title of study exactly as it appears on the Western Protocol

Document Title

Add particular study subgroups to the document title, as applicable. This enables everyone to differentiate between consent forms and groups within a study (e.g., student group, teacher, parent).

E.g., Letter of Information and Consent – Student

Principal Investigator + Contact

Enter the Principal Investigator’s name, with title and telephone number.

E.g., **Principal Investigator**
Dr. John Doe, PhD, Psychology
Western University, X80000

Additional Research Staff + Contact (optional)

You may choose to enter names and titles of Additional Research Staff, but this is not required. Please note: if you do enter names and titles, it will be necessary to submit a revised Consent Form and Western Protocol for review and approval any time personnel changes.

E.g., **Additional Research Staff**
Dr. Mary Jones, PhD, Anthropology
Dr. James Wright, MA, Ivey

1. Invitation to Participate

Introduce the research, invite the potential participant to participate, indicate why the participant is being approached, and why this research is being done.

E.g., **Introduction**
You are being invited to participate in this research study about [explain what the study is about] because you [explain WHY the individual is being approached and asked to participate].

2. Why is this study being done?

- 2.1. Provide background information on what prompted the need for this study
- 2.2. Do not state that “This study has been **approved** by the research ethics committee...” since this may appear to offer a guarantee of safety. Western University’s REB will not approve this wording in the letter of information or any study documents.

2.3. Explain the purpose of the study in lay terminology

E.g., The purpose of this study is to [indicate why the study is being done and your objectives].

3. How long will you be in this study?

3.1. Include the anticipated length of the study the number of study visits and how long each study visit will take.

E.g., It is expected that you will be in the study for [length of study - [# days/weeks/months/years], there will be [#] study visits during your participation in this study and each visit will take approximately [# of hours].

3.2. Include the number of people to participate.

Up to [#] people will participate in this study and we anticipate that up to [#] will be enrolled at this institution.

4. What are the study procedures?

The Procedures section should outline what is expected of the participant. This section should be exceptionally clear so that the participant is clearly informed of his/her responsibilities.

Consider inserting a table of study procedures/time commitments to assist participants in understanding what they are agreeing to.

E.g., If you agree to participate you will be asked to [the following items are things to consider when writing this section of the Consent document]:

- 4.1. If applicable, list the different types of study visits to take. Include what is required of the participant at each of these visits.
- 4.2. If applicable, information on Audio / Video-recording. If Audio / Video-recording is being used the participant must know if they can still participate if they do not agree to be recorded. If there is an option, a check box must be added to the Consent Form to accompany this section.
- 4.3. Location of the study
- 4.4. Nature of measures

Some description of the type of measures may also be needed. If the measures involve potentially sensitive or personal questions (e.g., sexual practices, IQ measures, illegal activities, etc.---these are just a few examples and the researcher should consider whether they feel the participant's willingness to participate might be affected by the nature of the questions). There is recognition that in some cases full disclosure about the nature of the measures might compromise the

integrity of the data. If the researcher believes this to be the case he/she should address it in the protocol.

5. What are the risks and harms of participating in this study?

Outline possible risks and harms here as per your protocol submission, or if there are none, indicate that here.

E.g., The possible risks and harms to you include [insert possible risks and harms here].

OR

E.g., There are no known or anticipated risks or discomforts associated with participating in this study.

If there is a risk of emotional upset or distress and/or non-emotional risks/harms, please include a list of local (local to where the research is taking place) resources.

If you are collecting personal identifiers, please disclose that there is always the risk of a privacy breach.

6. What are the benefits?

Outline possible benefits to the participants and to society as per your protocol submission. You may indicate there are no benefits to the participant but there should always be societal benefits.

E.g., The possible benefits to you may be [insert benefits here]. The possible benefits to society may be [insert societal benefits here].

OR

E.g., You may not directly benefit from participating in this study but information gathered may provide benefits to society as a whole which include [insert societal benefits here].

7. Can participants choose to leave the study?

Insert information on the participant's right to request the withdrawal of data including any limitations on the feasibility of that withdrawal.

If withdrawal of data is possible when the participant withdraws from the study, insert the following:

E.g., If you decide to withdraw from the study, you have the right to request (eg., written, calling, etc.) withdrawal of information collected about you. If you wish to have your information removed please let the researcher know. It is important to note that a record of your participation must remain with the study as such, the researchers

may not be able to destroy your signed letter of information and consent, or your name on the master list, however any data and/or samples may be withdrawn. **NOTE:** once the study has been published we will not be able to withdraw your information.

If withdrawal of data is not feasible (e.g., when personal information has been anonymized and added to a data pool) and the PI will continue to use the participants' data after they have withdrawn from the study, insert the following:

E.g., If you decide to withdraw from the study, the information that was collected prior to you leaving the study will still be used as the researchers will be unable to identify an individual participant's responses. No new information will be collected without your permission.

8. How will participants' information be kept confidential?

Describe the protection of the participant's privacy, indicate what identifiable information will be collected, method of storing research data, where the data will be stored, how long it will be stored, who will have access to the information collected for the study and how it will eventually be destroyed. Ensure that it is clear who has access to what type of information.

NOTE: This information must be consistent with the data security and confidentiality information included in the ethics application.

8.1. Indicate if people/groups/organizations outside the study team will have access to information collection (e.g., including transcription company, community partners, etc.).

E.g., Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held to check that the information collected for the study is correct and follows proper laws and guidelines. They may also be given remote access to these records through the internet via secure video conference or through redacted (personal identifiers blacked out) copies

Examples include:

- The Quality Assurance and Education Officers from the Hospital's Office of Research Services
- Representatives of the Western University and its Health Sciences Research Ethics Board that oversees the ethical conduct of this study. (Note: This statement is always required and must be included in LOI.)

- 8.2. **If identifiable information must be collected (e.g., date of birth and initials) it must be made very clear that in doing this the participant may be identified, this is also true for research in small populations where triangulation may occur.**

It should be clear:

- a) what identifiable information (direct or indirect) is being collected, why, and who will have access?
- b) what, if any, identifiable information (direct or indirect) is going to be disclosed in dissemination?
- c) what options are available for the way in which these identifiers are used (e.g., consent to use name, consent to use direct quotes, consent to use position/title, consent to use photos, etc.)?

E.g., While we do our best to protect your information there is no guarantee that we will be able to do so. The inclusion of your [e.g., initials and date of birth] may allow someone to link the data and identify you.

- 8.3. **If using tele/video conferencing include wording regarding potential risk of these platforms. For example, teleconferencing/videoconferencing technology has some privacy and security risks. It is possible that information could be intercepted by unauthorized people (hacked) or otherwise shared by accident. This risk can't be completely eliminated. We want to make you aware of this.**

- 8.4. **If identifiable information will be shared with others outside the study team please clarify what information will be disclosed and with whom it will be shared.**

Note: If there is planned disclosure of personal identifiers, or if they are used on any research-related information/documents, or if they are part of the unique identifier, this must be justified in the REB application and approved.

- 8.5. **Include how long identifiable information will be kept.**
The researcher will keep any personal information about you in a secure and confidential location for [##] years ([Western's Faculty Collective Agreement research data retention policy is 7 years](#)). A list linking your study number with your name will be kept by the researcher in a secure place, separate from your study file.

- 8.6. **Include a statement that participants will not be named in any reports, publications, or presentations that may come from this study.**

E.g., If the results of the study are published, your name will not be used

- 8.7. **For studies which include focus groups please add the following statement**

“Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to

remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.”

- If the data is to be professionally archived, a description of where it will be archived and who may have access to the archive is needed.
- 8.8. If the researcher wishes to use personal quotes, titles, names or other identifying information within the publication, this must be made clear. There must also be a check box on the Consent Form to accompany this section. A check box is required for the use of directly identifiable quotes and even for quotes which are not directly attributable to an individual.
- 8.9. **Re: open access data:**

If you anticipate data may be made available to journals and/or other researchers (e.g., for replication studies and/or re-analysis for different research questions) then participants must be informed of this in the Letter of Information and Consent (LOI/C), as well as what type of information will be shared. NOTE: Indicating that all information will be kept confidential to the researchers will restrict you from sharing this information (even if anonymized) outside of the research team in the future.

Example:

All identifiable information will be deleted from the dataset collected so that individual participant's anonymity will be protected. The de-identified data will be accessible by the study investigators as well as the broader scientific community. More specifically, the data [will/may be posted on specific database OR made available to other researchers upon publication] so that data may be inspected and analyzed by other researchers. The data that will be shared on [insert database/publication] will not contain any information that can identify you.

See Open Access Guidance Document for more information.

- 8.10. **Re: Future use of data:**
- The future use of data for secondary purposes (for a new purpose beyond the specific objectives of the original project) requires:
- a) separate REB oversight or exemption at the time of the future research and
 - b) broad consent.

This is distinct from open-access data sharing. Broad consent is defined as consent for future unspecified research. Unlike blanket consent, which is typically unrestricted, broad consent always includes specific restrictions (e.g., consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry). Broad consent applies to the storage and secondary use of participants' data and/or human biological materials collected for research purposes. The use of broad consent is in the context of future

research being conducted using data and/or human biological materials with no direct contact, consent, or intervention with the participants who provided the data and/or biological materials at that time. While blanket consent is not permitted under the TCPS, broad consent is permitted. Broad consent MUST be optional and contain all information outlined in TCPS2 Article 3.13 (see interpretation https://ethics.gc.ca/eng/policy-politique_interpretations_consent-consentement.html).

Optional Broad Consent for Future Secondary Use of Data

Example:

Please note that researchers will have to make the text in *[brackets]* specific to their consent.

We wish to use your *[de-identified, identifiable, anonymous, anonymized]* data *[and/or biological specimens]* for future research related to *[scope]*. While such research is not planned at this time, it is possible that we may use *[and/or share your data with other researchers {at this institution/in Canada/around the world}]* in the future. Once data is shared, it cannot be withdrawn *[or if it can be, explain the mechanism to do so]* . *[If data will be entered into a formal repository, please describe oversight and governance]*. It is unknown at this time what the risks of any future research are *[if there are known risks such as to genetic research, please state the risks. Any risk of re-identification or incidental findings and how they will be managed need to be disclosed]*. You may not personally benefit but the future research will contribute to knowledge about *[scope]*. Participation is optional and it will not impact your participation in the current study. A location to indicate your decision is provided on the last page of this document. You *[will/will not/may choose to be]* be contacted about this future research [\[matching option for future contact should be provided on signature page of LOI\]](#).

Example:

We wish to use your de-identified data for future research related to stress and heart development in children. While this research is not planned at this time, it is possible that we may share your data with researchers around the world. Once data is shared, it cannot be withdrawn. It is unknown at this time what the risks of any future research are, and your data may be combined with other data that may re-identify you to other researchers. You will not personally benefit but the research will contribute to knowledge about heart development. Participation is optional and it will not impact your participation in the current study. A location to indicate your decision is provided on the last page of this document. You will not be contacted about this future research.

- 8.9 [If using a third party for data collection, storage, or transfer \(for example Qualtrics, REDCap, NVIVO etc.\) please include the following information \(at a minimum\), as applicable:](#)

- Use of 3rd party
- Name of 3rd party
- Link to 3rd party's privacy policy
- Country where data is stored using 3rd party (do not need to include Western storage location once exported from 3rd party platform)
- Identify risks (i.e. nothing over the internet is ever 100% safe)

9. Are participants compensated to be in this study?

Include whether participants will incur any expenses as a result of their participation in the study.

Compensation = base amount given to all participants
Reimbursement = to cover accrued expenses
Incentives = performance-based on top of compensation

If compensation will be in the form of a draw review Appendix A below, for guidance on what is required.

Include how reimbursement will be pro-rated if participants withdraw early from study.

E.g., You will be compensated [insert what the compensation is, if applicable] for your participation in this study. If you do not complete the entire study you will still be compensated at a pro-rated amount of [indicate the pro-rated amount and how it will be offered].

OR

E.g., You will not be compensated for your participation in this research.

10. What are the Rights of Participants?

10.1. You must include the following statements:

Your participation in this study is voluntary. You may decide not to be in this study. Even if you consent to participate you have the right to not answer individual questions or to withdraw from the study at any time. If you choose not to participate or to leave the study at any time it will have no effect on your [care/employment status/academic standing - choose only those that are applicable].

You do not waive any legal right by consenting to this study.

11. Whom do participants contact for questions?

Instructions on whom (name and phone number) to contact regarding any questions or concerns that may be raised by participating in the study or questions that may be raised by being a research participant. Note, the Principal Investigator must be listed as the primary contact, the research assistant or a student may also be listed in addition to the PI.

E.g., If you have questions about this research study please contact [Principal Investigator: Name, Contact Information].

You must also include:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics (519) 661-3036, 1-844-720-9816, email: ethics@uwo.ca. The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential.

Or

If this is a study that requires LHSC/SJCH institutional oversight:

The Letter of Information should include the following language for St. Joseph's Health Care London as a contact outside of the research team:

If you have any questions/concerns about your rights as a research participant or the conduct of this study, please contact: St. Joseph's Health Care London Patient Relations Consultant at 519-646-6100 ext. 64727

The Letter of Information should include the following language London Health Science Centre as a contact outside of the research team:

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036.

This letter is yours to keep for future reference.

12. Consent

Implied Consent

If your study will use implied consent (As requested and justified in ethics application) add one of the following examples to obtain Implied Consent to the end of your letter of information.

E.g., Completion of the survey is indication of your consent to participate.

OR

E.g., You indicate your voluntary agreement to participate by responding to the questionnaire / survey / etc.

Verbal Consent

If your study will use verbal consent (that is, you are not receiving written consent for a justifiable reason as outlined in the REB application), please include a verbal recruitment script that you will read to the participant to obtain their consent (see example below).

Please note verbal consent must be documented (e.g., on audio-recording, or by researcher checking the appropriate boxes on behalf of participant).

Written Consent

If your study will use written consent (that is you are carrying out the study procedures face-to-face) include this section with the rest of the LOI document, but on its own page.

1. Project Title

2. Document Title

3. Principal Investigator + Contact

4. Additional Research Staff + Contact (optional)

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.

IF APPLICABLE INCLUDE THE FOLLOWING:

WHEN YOU INTEND TO SEEK BROAD CONSENT FOR FUTURE SECONDARY USE OF DATA/SPECIMENS

If you wish to ask participants to provide broad consent for future use of data (See Section 8.10), please provide initial boxes before the “Participant’s Signature” block for participants to accept or decline to have their data/specimens used in the future. See example below:

CONSENT FOR FUTURE USE

Please check and initial the appropriate box below:

I agree to have my data [*and/or specify biospecimen*] used in future research studies

I do NOT agree to to have my data [*and/or specify biospecimen*] used in future research studies

WHEN YOU INTEND TO RECONTACT FOR FUTURE RESEARCH

If you wish to ask participants to consent to future contact for additional studies, please provide initial boxes before the “Participant’s Signature” block for participants to accept or decline to be contacted for other studies in the future.

See example below:

CONTACT FOR FUTURE STUDIES

Please check and initial the appropriate box below:

I agree to be contacted for future research studies

I do NOT agree to be contacted for future research studies

IF APPLICABLE INCLUDE THE FOLLOWING:

If the participant has an **option** of being audio or video-recorded, insert the following into the Written Consent template:

I agree to be audio recorded in this research (initial the appropriate box)

YES NO

I agree to be video recorded in this research (initial the appropriate box)

YES NO

IF APPLICABLE INCLUDE THE FOLLOWING:

If you are including personal quotes or names in your publication, insert the following into the Written Consent template:

NOTE: These must only be provided as options IF disclosed in the ethics application AND described in the confidentiality section of the LOI.

I consent to the use of personal, identifiable quotes obtained during the study in the dissemination of this research. Initial the appropriate box.

YES NO

I consent to the use of unidentified quotes obtained during the study in the dissemination of this research. Initial the appropriate box.

YES NO

I agree to have my name used in the dissemination of this research. Initial the appropriate box.

YES NO

IF APPLICABLE INCLUDE THE FOLLOWING:

If participants are able to provide written consent, insert the following:

Print Name of Participant

Signature

*Date (DD-MMM-
YYYY)*

REQUIRED FOR WRITTEN CONSENT:

The person obtaining consent must also sign the consent form. Please insert the following:

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person
Obtaining Consent

Signature

*Date (DD-MMM-
YYYY)*

IF APPLICABLE INCLUDE THE FOLLOWING:

If the study involves children, you may also need to obtain Assent from the child. Please see the Assent Letter Guidance Document.

Child's Name: _____

Parent / Legal Guardian / Substitute Decision Maker (Print): _____

Parent / Legal Guardian / Substitute Decision Maker (Sign): _____

Parent / Legal Guardian / Substitute Decision Maker (Date): _____

IF APPLICABLE INCLUDE THE FOLLOWING:

If you are including people with communication difficulties, insert the following into the Written Consent template:

Was the participant assisted during the consent process?

YES NO

If **YES**, please check the relevant box and complete the signature space below:

The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Print Name of Translator

Signature

Date (DD-MMM-YYYY)

Language

IF APPLICABLE INCLUDE THE FOLLOWING:

If you are including illiterate people (those who cannot read English), add the following:

The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and has had any questions answered.

Print Name of Witness

Signature

Date (DD-MMM-YYYY)

Relationship to Participant

Appendix B: Guidance on Lotteries, Raffles and, Draws

General information: There are various federal laws including Criminal Code of Canada, Competition Act, and provincial laws that apply to lotteries. When proposing to offer a research-related draw as a form of compensation, researchers should keep this guidance in mind to minimize the likelihood of triggering legal issues.

Guidance

- a. Researchers should use the term “draw” rather than “lottery” or “raffle,” since the latter terms imply purchase of tickets by participants.
- b. To further avoid the possibility that a draw would be perceived as a lottery, the researchers should permit all individuals who are contacted concerning the research to enter the draw. This would encompass individuals who are invited to participate but decline, prospective subjects who are ineligible, and subjects who enroll but later withdraw/are withdrawn by the researchers. Additionally, the researchers should permit any individual who asks to be included in the draw to be included in the draw. These steps would be the equivalent to a “no purchase necessary” option seen in most commercial draws and would demonstrate that no consideration was required to participate in the draw. ¹

¹ Note that it is possible that individuals may abuse the draw or commit fraud. Examples may include the use of bots to enter the draw or participants using multiple identities to obtain multiple draw entries. In

- c. Both the amounts and number of prizes should not be coercive or exert undue influence on participants. Some universities specify that the prize is not to exceed \$500. Several low value prizes are preferred over one high value prize.
- d. You cannot require participants to pay money or other valuable consideration to participate in the draw.
- e. If personal information is collected solely for the administration of the draw, the researcher should maintain security of this information throughout the duration of the study and should destroy it once the prize is awarded.
- f. The draw should be conducted in a manner that does not otherwise compromise participant anonymity or confidentiality that is protected by other protocol methodology.
- g. All participants who are interested in being considered for a draw should have the same chance of winning the prize(s).
- h. The researcher, any co-researchers or research assistants named in the protocol, their immediate family members and any other person with a direct interest in the research study should be excluded from participation in the draw.
- i. Participants should be afforded the opportunity to not participate in the draw.
- j. Social media companies (e.g. Facebook, Instagram, Twitter, etc.) may have specific requirements related to draws when a researcher uses the social media platform (i) as an active means of entering and participating in the draw; and/or (ii) to promote the draw. Researchers using a social media platform for a draw will have to identify and comply with these requirements. Note that these requirements may change from time to time.
- k. The protocol and consent document(s) should include the following information:
 - Description of the prizes, including estimated value, and the total number of prizes to be awarded.
 - The odds of winning a prize, if known, or explanatory language similar to this: “For any draw, the odds of winning a prize depend on how many people are entered in the draw. As we do not know how many people will participate in this study and related draw, we cannot predict what will be the odds of winning a prize.”

The approximate timing of the draw (e.g., month/year).

such cases, entry into the draw or the award of prizes may be voided. The REB has provided guidance on such scenarios [here](#).