

THE UNIVERSITY OF WESTERN ONTARIO
RESEARCH ETHICS BOARD FOR THE REVIEW OF NON-MEDICAL RESEARCH
INVOLVING HUMAN SUBJECTS
(NMREB)

INFORMATION AND CONSENT DOCUMENTATION GUIDELINES

*Requests for interviews with persons in authority need not follow such a structured outline.
(see Section 10.0 in the Guidelines.)*

INSTRUCTONS – INFORMATION & CONSENT DOCUMENTATION		
SECTION	RATIONALE & COMMENTS	PHRASING
	<ul style="list-style-type: none"> The participant must receive a copy of the Letter of Information or combined Information/Consent document 	
Title of the research	<ul style="list-style-type: none"> The formal title of the study heads this section. The form should include the exact title of the research protocol (i.e. Section 1.1 the title under which the research was approved and funded). When the title is cumbersome, a short simplified title may be added. 	
Identity of researchers & sponsors	<ul style="list-style-type: none"> Identity of researchers (and sponsors if funded by industry or a contract) must be included on the form. The name(s), degree(s) (and affiliation if other than the institution where the research is being conducted), and contact telephone number(s) If a researcher is a student this must be explicitly stated and the identifying information of the supervisor included This information should be listed below the title of the project The investigators should refer to themselves as the 'study investigator(s)' or 'study doctor(s)' to avoid confusion with the patient's usual physician 	<p>EXAMPLE</p> <p>I am a Masters student in the Department of Sociology at The University of Western Ontario and the information I am collecting will be used in my thesis.</p>

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Invitation to participate in research	<ul style="list-style-type: none"> Information that informs the individual that they are being invited to participate in <i>research</i>. Provide a brief description of the study, indicating that it is a research study or clinical trial, as appropriate. 	<p>You are being invited to participate in a research study looking at ...</p> <p>The purpose of this letter is to provide you with the information you require to make an informed decision on participating in this research.</p> <p>We are asking you to take part because you have indicated an interest in knowing more about...</p>
To whom the Consent Form should be directed	<ul style="list-style-type: none"> Use the pronouns “you” and “your” rather than “I” and “mine”. If there are competent and incompetent participants or if the participants are minors, the letter should be written and read as referring to the participant rather than the parent/guardian who is signing the consent form for the participant. Avoid the use of “you/the participant” or “your/the participant’s” phrasing in the documents. 	<p><i>(if applicable insert at beginning of letter/questionnaire/instructions etc)</i></p> <p>The pronouns ‘you’ and ‘your’ should be read as referring to the participant rather than the parent/guardian/next of kin who is signing the consent form for the participant.</p>
Summary explanation of research Purpose of study	<ul style="list-style-type: none"> The document should be written in language which can be understood by the research participant. It may be necessary to have the letter translated into another language if it is known that the subjects are unlikely to be fluent in English A brief description of the purpose of the research should explain what hypothesis is being tested and what the research is supposed to demonstrate. 	<ul style="list-style-type: none"> Use lay language and grade 8 reading level. Possible need for translations
Number of participants	<ul style="list-style-type: none"> Indicate the number of participants that will participate and if a multi-site study indicate number at local site and number nationally/internationally. 	Recommended but not required.

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Participant inclusion exclusion criteria	<ul style="list-style-type: none"> • Include inclusion/exclusion criteria if the recruiter would not know if a participant was eligible or if there could be consequences to a non-eligible person's participation in the study. 	<p>EXAMPLES:</p> <p>If your child is allergic to peanuts s/he must not participate in this project as we cannot guarantee that the snacks provided will be peanut free.</p> <p>If you are epileptic you must not participate in this study.</p>
<p>Description of the research</p> <p>Experimental procedures</p>	<ul style="list-style-type: none"> • Provide a clear understanding for the participant of how s/he will be involved in the research • Identify any procedures which are not part of normal care. Make a distinction between procedures that are part of standard routine and those that are mandated by the study design. • Explain if any current therapies or treatments are being altered or discontinued • Thoroughly describe all of the study procedures. • Identify any intervention(s), device(s), testing procedure(s) that will be used. When procedures are repeated, list the frequency and intervals concerned. This is often best enumerated in the form of a table. • If any of the study procedures, or devices are experimental, they must be identified as such. • If the participant will be interviewed or asked to complete a questionnaire, describe the types of questions that he/she will be asked to answer. • If a person's (health)(academic) record will be reviewed this too must be explained 	<p>If you take part in this study, you will be asked to do the following..</p> <p>These forms are routinely given to children enrolling in this program, and may be done even if you do not participate in the study...</p> <p>The following are experimental procedures that are being tested in this study...</p>

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Specific Research Techniques <ul style="list-style-type: none"> • Randomization • Blinding • Sequential Assignment 	<ul style="list-style-type: none"> • Specific research techniques must be explained to the participants. 	EXAMPLES: The participants in the study will be assigned at random, that is, by a method of chance, to one of the groups. You will have a (1 in 2 ; 3 in 4 etc) chance of being in group a or group b.
Estimate of participant's time	<ul style="list-style-type: none"> • An estimate of the total amount of time required on the part of the participant (number of sessions, frequency of testing, etc.). 	EXAMPLES: You will be asked to complete six questionnaires, one at each of the office visits. The questionnaire at the first visit will take approximately 30 minutes to complete, the other five questionnaires will only take 5 minutes each. You will have to go to the exercise lab in Thames Hall at 9 am every Friday morning for the next 4 weeks to have your weight checked. The weigh-in will take approximately 15 minutes to complete.
Location	<ul style="list-style-type: none"> • Indicate where the research will be conducted. 	EXAMPLES: The testing will take place in Room 155 at the Board of Education offices on Main Street. The interviewer will call you at home and ask you the questions over the phone.
Risks / Harms	<ul style="list-style-type: none"> • Describe all risks and discomforts (physical and psychological) and any reasonably foreseeable risks or discomforts to the participant. • Do not describe, in detail, the risks of the standard procedures the participant would undergo even if he was not a research subject -- include only those risks associated with the investigational aspects of the protocol. 	EXAMPLES: While answering some of the questions you may feel sad or upset. If this happens please tell the interviewer and she will discuss these feelings with you or provide you will some contacts if you would like counselling.

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	<ul style="list-style-type: none"> • Describe how serious the potential harm is • Describe how likely it is to occur • It is recommended that you list the physical and non-physical risks in two categories: likely and less likely, but serious – quantify if possible. • What will be done to prevent or minimize the probability of occurrence • Acknowledge the possibility of unforeseen harms • If applicable, include a statement that the treatment or procedure may involve risks, which are currently unforeseeable, to the participant or to the foetus or child, if the participant is or may become pregnant or is breastfeeding. • If there are no known risks include a statement to that effect. 	<p>The treatment or procedure may involve risks, which are currently unforeseeable, to you or to the foetus, if you are or become pregnant.</p> <p>There are no known risks to your participation in this study.</p>
Benefits	<ul style="list-style-type: none"> • Identify benefits to participant • If intervention is involved no beneficial effects are to be guaranteed • If no direct benefit to participant is anticipated include a statement to that effect • If there are potential benefits, describe as completely as possible, • how important are they and how likely are they to occur • An additional sentence/paragraph about possible benefits to society or science may also be inserted. This should be separate from the specific benefits. • N.B. Monetary compensation is <u>not</u> a benefit. 	<p>EXAMPLES:</p> <p>There are no known benefits to you associated with your participation in this research.</p> <p>You will not benefit directly from participation in this research.</p> <p>You will not get a personal I benefit from participating in this study but your participation may help us get new knowledge that may benefit future students experiencing difficulties in first year.</p>

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Voluntary participation Refusal to participate Discontinuing Participation Withdrawal from study <ul style="list-style-type: none"> • By participant • By investigators or sponsor 	<ul style="list-style-type: none"> • Normally the participants must freely consent to participate; participation is voluntary; participants may choose not to participate at all, may refuse to participate in certain procedures or answer certain questions or may discontinue the experiment at any time without penalty or loss of benefits to which the participant is otherwise entitled. • Emphasize that the decision to participate, or not participate, is solely up to the participant. • In those instances when it is not possible for a participant to withdraw from the research this should be explained. • It is also important to advise participants that withdrawal of their participation does not necessarily include withdrawal of any data compiled up to that point. • When applicable, participants should be informed of circumstances under which their participation may be terminated by the investigator without the participant's consent. • Participants should also be informed of procedures for safe and orderly termination should they decide to withdraw from the study before it is completed 	REQUIRED WORDING: Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future (care/ academic status/ employment etc). (additional REQUIRED WORDING for Student Course projects) This project is an opportunity to give students experience in doing research, it is a training and teaching exercise. Please note that it will not affect my grade if you decide that you do not want to participate; or decide to withdraw part way through the study EXAMPLES: You have the right to be given all important information about your treatment, the study and what you will be asked to do. You should only agree to take part if you feel happy that you know enough about these things. You do not have to take part in the study if you do not want to. If you decide to withdraw from the study, or if you are withdrawn from the study before it is completed you may be asked to (e.g. return to the office for a final evaluation etc)

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Participation in concurrent or future studies	<ul style="list-style-type: none"> • It is important to determine if participants are already part of an ongoing study and may be compromised by participation in this study • On occasion, participation in a study will knowingly involve the participant with a predictable chance for involvement in further studies • If this is the case participants should be provided with this information and told they will have the opportunity to decide if they want to participate at a later date • Concurrent studies for tissue or blood banking will require a separate consent form 	<p>EXAMPLES:</p> <p>If you are already participating in an other study at this time, please inform the interviewer right away to determine if it is appropriate for you to participate in this study.</p>

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Specimens or Human Tissues	<p>Indicate</p> <ul style="list-style-type: none"> • what the sample(s) are to be used for <ul style="list-style-type: none"> - Current study only - Future unknown research (banking) • where and how the samples will be stored • whether or not the participant will receive the results of the testing • if they will be linked to the participant • how long they will be stored • how they will be disposed of • describe the possibility for commercialization of research findings and what the subject may expect in way of compensation • <i>Consent for future unknown research and/or general banking of blood or tissues must have a separate Information/consent document.</i> 	<p>EXAMPLES:</p> <p>Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the researchers/sponsors and once you have provided the specimens you will not have access to them.</p> <p>The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol.</p> <p>The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the researchers/sponsor. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.</p>
New Findings	<ul style="list-style-type: none"> • Participant must be given continuing and meaningful opportunities for deciding whether or not to continue participation. • The inclusion of this statement is mandatory in clinical trials. 	<p>EXAMPLE:</p> <p>If, during the course of this study, new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the investigator.</p>

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Anonymity	<ul style="list-style-type: none"> Anonymity can only be protected when the researcher will have no way of connecting data to individuals. Names or other easily identifiable elements should not be noted directly on questionnaires or documents that would be sent to sponsors (e.g. patient reports) 	
Confidentiality	<ul style="list-style-type: none"> Describe the protection of the participant's privacy, method of storing research data, and who may have access to study records. The documents should not contain language that may be construed as requiring the participant to consent to unfettered access to his or her medical records by third parties. The monitor(s), the auditor(s), the REB and regulatory authority(ies) will be granted direct access to the participant's original records for verification of clinical trial procedures and /or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations. The participant or the participant's legally acceptable representative, by signing a consent form is authorizing such access Access may have to be granted to ensure the integrity of the study, to ensure participant health and welfare and maintenance of high standards Since there are situations in which a researcher may be compelled to break the confidentiality of 	<p>EXAMPLES: Your research records will be stored in the following manner: locked in a cabinet in a secure office; video tapes will be viewed only by members of the research team and they will be destroyed after 2 years.</p> <p>If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure.</p> <p>Your confidentiality will be respected. No information that discloses your identity will be released or published with your specific consent to the disclosure. However, it is important to note that the original signed research consent form and the data which will follow, will be included in your school record.</p> <p>Representatives of (research team, reb, authorized study personnel, the study sponsor (identify), and regulatory bodies (identify) may require access to your records for the purpose of monitoring the</p>

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	<p>(e.g. in response to a subpoena), absolute guarantees are not possible.</p> <ul style="list-style-type: none"> Participant’s privacy will be protected to the maximum extent allowable by law 	<p>research.</p> <p>The Research Ethics Board at The University of Western Ontario may contact you directly to ask about your participation in the study.</p> <p>If we find information we are required by law to disclose, we cannot guarantee confidentiality.</p> <p>We will strive to ensure the confidentiality of your research-related records. Absolute confidentiality cannot be guaranteed as we may have to disclose certain information under certain laws.</p>
<p>Alternative treatments</p> <p><i>(If appropriate)</i></p>	<ul style="list-style-type: none"> Include applicable information on alternative procedures or courses of treatment that may be available to the potential participant if he/she refuses to participate or withdraws from the study. It is not enough just to indicate that there are alternatives, they must be described. Particularly in the case of therapeutic interventions identify the care to be provided if the participant declines to participate. Include a summary of the nature of the alternative and potential harms and benefits. If a treatment is involved, no beneficial effects are to be guaranteed; in the case of experimental treatment, participants are to be informed of alternative or standard treatments available and their record of success. 	<p>EXAMPLES:</p> <p>Regardless of your decision to participate you can still receive continuing care through this centre.</p>

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Contact person(s) for participants	<ul style="list-style-type: none"> • Instructions on whom (name and phone number) to contact regarding any questions or concerns that may be raised by participating in the study. The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research. • The form should contain contact information other than the research team for participants with questions regarding the conduct of the study and/or their rights as research participants. For hospital or research institute based studies this would be the Vice President Research or comparable position. 	<p>REQUIRED: If you have any questions about this study or your care/ treatment please contact ... Study investigator(s), staff + telephone numbers</p> <p>EXAMPLE If you have questions about your rights as a research subject you may contact: <i>The Office of Research Ethics</i> <i>The University of Western Ontario</i> 519-661-3036</p>
Compensation & Costs to Subjects	<ul style="list-style-type: none"> • If participants will be compensated for their participation or reimbursed for costs (e.g., parking), describe in detail the type of payment, amount, and terms. • If participant does not complete the study compensation should be prorated. • If there is to be no compensation include a statement to that effect. • Specify any additional costs to the participant that may result from participation in this study that will not be reimbursed. 	<p>EXAMPLES You will not be paid to take part in the study; however, you will be reimbursed for your expenses such as parking for visits required as part of this study.</p> <p>In the event you are not able to complete the study your compensation will be pro-rated accordingly.</p> <p>You will not be compensated for your participation in this research study.</p> <p>Additional costs you may incur as a result of your participation are: (e.g. parking, drug costs, child care etc)</p>

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No waiver of rights	<ul style="list-style-type: none"> There should be <u>no exculpatory language</u> whereby the participant waives or appears to waive, any of his/her legal rights, including any release of the sponsor, institution or its agents from liability for negligence. 	You do not waive any legal rights by signing the consent form.
No institutional approval	<ul style="list-style-type: none"> There must be <u>no indication</u> that UWO or its affiliated institutions have approved the research as this may unduly influence a potential participant's decision to participate 	
Publication of results	<ul style="list-style-type: none"> The ways in which the research results will be published, And if appropriate, how the participants will be informed of the results. 	<p>If the results of the study are published, your name will not be used.</p> <p>If you would like to receive a copy of the overall results of this study please put your name and address on a blank piece of paper (separate from the questionnaire) and give it to the interviewer.</p>
Conflict of Interest	<ul style="list-style-type: none"> When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study. If the investigator has a significant financial interest in the outcome of this particular study or research program, a statement to that effect should be inserted. This would include shares in the sponsoring company and remuneration for the recruitment of the participant. 	
Language Level	<ul style="list-style-type: none"> Lay language Grade 8 level recommended 	

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Formatting	<ul style="list-style-type: none"> • Use simple declarative statements. • Write short sentences/ use short paragraphs • Use of “you <i>understand</i> that” is not permitted as it could be interpreted as suggestive and can constitute coercive influence over a subject. 	
	Type size	<ul style="list-style-type: none"> • 14 point recommended but larger type may be needed for elderly or visually compromised participants • Avoid italics or ornate type
	Page layout	<ul style="list-style-type: none"> • Use bullets, tables, charts • The use of ‘white space’ makes the document easier to read.
	Page header or footer	<ul style="list-style-type: none"> • Number each page • Study title or reference & version number • Date • Place for participant initials

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	Use headings and subheading frequently	<p>Suggested Headings</p> <ul style="list-style-type: none"> • Introduction • Purpose of this study • Research tests or procedures for this study • Risks and discomforts to you if you participate in this study • The benefits to you if you take part in this study • What will happen to the samples or information that are collected • Other pertinent information • What costs are there to you if you enter this study • What to do if you want to withdraw from this study • Specific things you should know about confidentiality • How long will this study last and how many people will be enrolled.
Consent Statement	<ul style="list-style-type: none"> • The Letter of Information and Consent Form may be combined as one document • The consent statement should be at the end of the combined Information/Consent document • The subject must receive a copy of the Letter of Information or Information/Consent document 	<p>REQUIRED WORDING</p> <p>I have read the Letter of Information (or Information/Consent document), have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.</p>

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Signatures	<ul style="list-style-type: none"> • Include a “Legally-Authorized Representative” signature line only if participants cannot consent on their own behalf. • The signature of a witness is optional but it is <u>not</u> required by law. A “Witness” signature line may be required by the Sponsor. • Form should be co-signed by the person responsible for obtaining informed consent • Children over 7 are encouraged to sign their name – alternatively they may sign an Assent form. (see Guidelines - Children Assent forms) • Participants should initial each page <p>Blind, illiterate or non-English speaking subjects</p> <ul style="list-style-type: none"> • When consent is given following reading/translating of the information/consent documents by someone other than the participant, that person should sign the consent form indicating their role in the consent process 	<p>REQUIRED:</p> <ul style="list-style-type: none"> • Research participant or legally authorized representative • Person responsible for obtaining informed consent <p>NOT RECOMMENDED</p> <ul style="list-style-type: none"> • Witness signature <p>REQUIRED:</p> <ul style="list-style-type: none"> • Person translating or reading document
Written consent not required	<ul style="list-style-type: none"> • In some cases, such as a survey or questionnaire, it is not necessary to have the subjects sign a consent form as the act of completing the questionnaire is taken to be the consent. • The investigator must incorporate the elements of a Letter of Information in a cover letter or face sheet to a written questionnaire. 	You indicate your voluntary agreement to participate by completing and returning this questionnaire.