INFORMED CONSENT PROCESS

AND CHECKLISTS

Ontario Shores Centre for Mental Health Sciences
and Abilities Centre Joint Research Ethics Board

CONTENTS

PROCESS OF OBTAINING CONSENT FOR A RESEARCH STUDY

Obtaining consent for research is an on-going process and the consent form document(s) is only one step in the process. The consent form is a record of the process between potential research subjects and the person obtaining the consent. Only current versions of consent forms approved by a Research Ethics Board (REB) should be used.

Key components of consent that respect the research participants and their autonomy are disclosure, capacity and voluntariness. All relevant information required for a potential research participant to make an informed decision is necessary and should be disclosed. If the research participant is not capable of providing consent, a substitute decision making can provide the consent. Where doubt exists about a potential research participant's competency to provide an informed consent, a competency assessment should be performed by a psychiatrist not associated with the study. A research participant's freedom, autonomy and independence are respected when the consent obtained is voluntary. To help ensure this, actual or perceived coercion can be avoided by having the potential research participant approached by an individual who does not have a treating relationship with them for the purposes of obtaining consent or to discuss the study.

Consent must be obtained from a research participant prior to starting a research study. When consent is obtained the study investigator should keep the original signed consent form and the participant should be offered a copy of the consent to keep. It is recommended that the copy provided to the participant can be stamped as 'Patient Copy.' A research participant has the right to withdraw consent at anytime during the research. A copy of the signed consent form must be provided to the participant.

To protect the potential research participant's privacy and confidentiality, discussion of the research study should take place in a quiet location. Potential participants should be encouraged to ask questions and to be offered the opportunity to take the consent form home to discussion with others such as family members and their family physician. Ample time must be allowed for them to make a decision on whether to participate or not.

Information Sheet

An information sheet may be used instead of a consent form in the following situations:

1. When enrolling subjects who are illegal drug users and may want complete anonymity.
2. In some questionnaire and survey research an information sheet may be acceptable as the act of completing the questionnaire or survey may be implied consent.

Third Party Consent (consent of next-of-kin)

This type of consent is usually obtained for studies that cannot be conducted with a consenting population and in which there is potential benefit to the subject.

Assent Form

An assent form should be provided for subjects under age 16 years of age. The assent form should be a simplified version of the consent form. Parental consent is required.

INFORMATION & CONSENT FORM CHECKLIST

It is highly encouraged that an electronic copy of the consent form be submitted, if possible.
Please submit signed electronic documents to the JREB office. Any hardcopies of documents requiring signatures can also be delivered to the JREB office. Please mention Rebecca Greenberg, Chair, Ontario Shores and Abilities Centre JREB (Phone # 905-430-4055 x 6004) as the JREB contact name for any questions by subjects regarding their rights as participants and ethical concerns in the research study.

Check	N/A	GENERAL
☐	☐	The consent form should be on institutional letterhead, with institutional logos included for all institutions/organizations involved in the research
☐	☐	At the top of the first page of the consent form the following should be included: the full Study Title; Protocol number (if applicable); Principal/Local Principal Investigator(s) name; Sponsor and funding sources; and contact information (if applicable).
☐	☐	The footer of the consent form and each page must be numbered (i.e. Page x of y) and the current version date must be included (i.e. yyyy-mm-dd).
☐	☐	The consent form should be written in the second person (i.e. "you"/"your") except the signature section should be in the first person singular (i.e. "I", "Me" "My").
☐	☐	Lay language should be used and preferably at no higher than a grade-8 reading level. Terms such as "randomization", "double-blind" and "placebo", should be explained in simple language, assuming no familiarity with a technical vocabulary.
☐	☐	Spelling, grammar and punctuation should be checked.
☐	☐	The format should enhance readability; recommended font style is Time New Roman or Arial; the font size should be 12 and can be larger if the research participants are from the elderly population.
☐	☐	Acronyms, short forms and abbreviations should be spelled-out and/or defined.
☐	☐	Avoid using acronyms in the consent form that form actual words while abbreviating the study title. This is to avoid the possibility of unduly influencing research participants and to avoid giving participants the expectation of a favourable outcome (i.e. the "W.O.N.D.E.R. D.R.U.G.: Study).
☐	☐	If the researcher is receiving a fee for enrolling participants this must be included in the consent.
INTRODUCTION		
☐	☐	Include a statement about what is involved in the study.
☐	☐	Include the statement, "You are being invited to voluntarily participate in a research study because …" The reason for being asked to participate should be included.

☐	☐	If an investigational agent is used, state if it has not been approved for this indication by Health Canada (Division 5) although it has been approved for use in this study.
WHY IS THE STUDY BEING DONE?		
☐	☐	Include a description of the purpose of the research study (hypothesis, objective, research question).
NUMBER OF PARTICIPANTS DURING THE STUDY		
☐	☐	State the approximate number of participants in the study and whether the study is multi-centered.
WHAT IS INVOLVED IN THE STUDY?		
☐	☐	Describe the intervention, treatment, drugs, dosage and frequency (as applicable).
☐	☐	Include the availability of treatment following the study.
☐	☐	If the study involves randomization then describe the randomized groups and the probability of random assignment (if applicable). The term 'randomization' should be used.
☐	☐	What procedures, medical tests and trial treatment (including invasive treatment) are involved? Describe only procedures specifically being done for research.
☐	☐	Include a study treatment table/schema.
☐	☐	Describe the experimental aspect of the study.
☐	☐	Describe the research participant's responsibilities (i.e. questionnaire completion).
MANDATORY SAMPLE/TISSUE COLLECTION		
☐	☐	State the purpose of the tissue collection.
☐	☐	Indicate the type and amount of tissue to be collected as well as the collection site.
☐	☐	How will the tissue be taken? How invasive is it? Are there safety issues around its acquisition? What are the conditions of the preservation of the tissue?
☐	☐	Indicate any identifying information on the sample and the safeguard in place to protect the participant's privacy and confidentiality.
PARTICIPANT'S LENGTH OF STAY IN THE STUDY		
☐	☐	Include the expected duration of the study and the length of the individual's commitment during the duration of the study.
☐	☐	Include foreseeable circumstances and reasons for termination of the research participant's participation.

RISKS		
☐	☐	Consent should be revised whenever an additional risk is identified during the course of the study and the participant should be re-contacted.
☐	☐	Foreseeable risks and discomforts, including long term.
☐	☐	Steps taken to minimize or treat the risks.
☐	☐	Include the name and contact information (i.e. phone number) of individuals to call to deal with and to report adverse events.
☐	☐	Risks should be categorized as follows: very likely/common (≥21%); less likely/occasional (5-20%); rarely (1-4%); as per the Investigator's Brochure (IB).
☐	☐	Minimal risk research should include an approved injury statement or compensation statement.
REPRODUCTIVE RISKS		
☐	☐	Include a statement to address the unforeseeable risks to the fetus or nursing infant of participant of child-bearing potential. Warnings should be included to advise not be become pregnant or to breast feed during the study.
☐	☐	Direction provided for participant to appropriate methods of family planning during the treatment period. The latter may apply to male also.
☐	☐	Indicate whether a pregnant partner release form will be used.
BENEFITS		
☐	☐	Describe the reasonable expected benefits of the study.
☐	☐	State if this is a non-therapeutic study (no intended clinical benefit).
☐	☐	State any reasonable expected benefits to others.
☐	☐	Avoid statements such as, "A benefit of this study is that DRUG X may help your medical condition."
ALTERNATIVES/OTHER OPTIONS		
☐	☐	Describe alternative treatment options if the participant chooses not to participate.
RIGHTS		
☐	☐	State that the participant can choose to not participate (withdraw) at any time without loss of benefit or without affecting the quality of their care.
☐	☐	State the consequences of the participant withdrawing and the steps to take if they want to withdraw (i.e. talk to Dr. first)
☐	☐	State what will happen to data already collected if the participant withdraws from the study.

☐	☐	State whether there is compensation available (or no automatic compensation) if the participant experiences a research-related injury.
☐	☐	State that the participant does not give up any legal rights or release the investigator, institution, sponsor, or their agents from liability for negligence.
☐	☐	A statement regarding the possibility of commercialization of research findings and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.
CONFIDENTIALITY		
☐	☐	State who will have access to the data collected on the identity of the participants [i.e. research team, REB, sponsor monitor(s), auditor(s), regulatory authority (Health Canada, FDA, etc.)] Explain that access to data will be done for the purposes of verifying trial procedures and/or data without breaching confidentiality to the extent permitted by law.
☐	☐	Explain how participant confidentiality will be protected to the extent permitted by law.
☐	☐	If information is released to a third-party state to whom the information will be provided, the nature of the information and the purpose of the disclosure.
☐	☐	For activities audio-taped or video-taped, describe the participant's right to review the tapes, who will have access, if they will be used for educational purposes and when they will be erased. Any audio/video taping, or photography must be addressed both in the consent form and in a separate audio/videotaping consent form.
☐	☐	When research results are published the participant's identity will be kept confidential.
☐	☐	Explain anticipated uses of the grouped/aggregated study data.
☐	☐	What are the ways in which research will be published?
☐	☐	What is the expected time of the availability of results and how will participants be informed of the results of the research.
COSTS/COMPENSATION		
☐	☐	Describe any costs to the participant (i.e. payment or reimbursement).
☐	☐	Is there any intent to pay subjects for their participation? Any anticipated expenses for participation (frequency of visits is higher than standard of care)?
☐	☐	• The following standard clause is recommended:

		(*For industry-sponsored studies*: "If you become ill or physically injured as a result of participation in this study, medical treatment will be provided. The reasonable costs of such treatment beyond that provided by your insurance will be covered by the sponsor,_____, for any injury or illness that is a direct result of participation in this trial. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.") OR (*For non-industry-sponsored studies*: "If you become ill or are physically injured as a result of participation in this study, medical treatment will be provided. In no way does signing this consent form waive you of your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.")
PARTICIPANT'S PROTECTIONS		
☐	☐	The study has been reviewed by a Research Ethics Board (REB) If new information becomes available that may affect the participant's willingness to participate then they need to be informed in a timely manner.
☐	☐	A Data Safety Monitoring Board will be reviewing the data for safety.
CONFLICT OF INTEREST		
☐	☐	Indicate the possibility of commercialization of research findings and the presence of apparent, actual or potential conflict of interest of the researchers, their institutions, or sponsors.
FUTURE RESEARCH		
☐	☐	If you anticipate that you may wish to re-contact study participants in the future for further research, please include this information in your initial consent form.
☐	☐	If you believe you may wish to use data from the study for future research please provide participants with as much information as possible about the future use of this data (*i.e., the type of research, protection of participant confidentiality, etc*.).
CONTACT INFORMATION FOR QUESTIONS & PROBLEMS		
☐	☐	The name and contact number of the principal investigator (PI) at Ontario Shores Centre for Mental Health Sciences. The PI can be contacted if a research related injury occurs. A 24-hour phone number as an emergency contact for participants to use if they cannot contact the PI (This is required for investigational drug studies).

☐	☐	Include a statement indicating that participants may discuss their rights as a participant and ethical issues in the research with the REB Chair, Rebecca Greenberg at (905) 430-4055 x 6004
CONSENT/SIGNATURE		
☐	☐	This section should be in the first person singular (i.e. "I", "Me" "My")
☐	☐	State that the participant will be provided with a copy of the signed consent form.
☐	☐	Include a statement about what the signature means. • Study explained to participant and all questions answered • Each page of the consent was read • Understand the expectations of being a participant • Understand the risks of the study • Authorize access to the participant's personal health information and study data as indicated in the consent • Agree to participate in the study
☐	☐	Participant's name, signature and date (yyyy-mm-dd)
☐	☐	Name, signature and date of person obtaining consent (serves as a witness)
☐	☐	Name, signature and date of person assisting with the consent process if applicable (i.e. translator or participant cannot read). An impartial witness is used if the participant or their representative is unable to read or if there is a concern about their level of understanding

GCP-ICH Clinical Trial Checklist

Key Elements Necessary for Clinical Trials as Required by Good Clinical Practice: Consolidated Guideline ICH Topic E6 (Section 4.8 Informed Consent of Trial Subjects)

4.8.4 None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

4.8.6 The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.

4.8.10 Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:

Check	
☐	a. That the trial involves research.
☐	b. The purpose of the trial.
☐	c. The trial treatment(s) and the probability for random assignment to each treatment.
☐	d. The trial procedures to be followed, including all invasive procedures.
☐	e. The subject's responsibilities.
☐	f. Those aspects of the trial that are experimental.
☐	g. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
☐	h. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
☐	i. The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.
☐	j. The compensation and/or treatment available to the subject in the event of trial-related injury.
☐	k. The anticipated prorated payment, if any, to the subject for participating in the trial.

☐	l. The anticipated expenses, if any, to the subject for participating in the trial.
☐	m. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
☐	n. That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.
☐	o. That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
☐	p. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
☐	q. The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
☐	r. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
☐	s. The expected duration of the subject's participation in the trial.
☐	t. The approximate number of subjects involved in the trial.

REFERENCES

1. Standard Operating Procedures for Obtaining Consent for a Research Study at CAMH

2. Singer, Peter A. Editor. Bioethics at the Bedside. Canadian Medical Association. 1999

3. The Ontario Cancer Research Ethics Board Study Information and Consent Form Elements. December 2007.

4. HHS/FHS & SJHH Research Ethics Board Consent Checklist

5. St. Joseph's Health Centre (SJHC): CONSENT FORM GUIDELINES. SEPTEMBER 2004