

HUMAN SUBJECTS RESEARCH ETHICS PROTOCOL FORM
REQUIRED CHECKLIST & GUIDANCE MATERIALS - CENTRE FOR
ADDICTION AND MENTAL HEALTH (CAMH)

- General Submission Guide**
- General Check List (all investigators must complete)**
- Check List for Protocols Involving Genetic Samples**
- Check List for Clinical Drug Trials (to be completed for both sponsor- and investigator-initiated trials)**
- Consent Form Requirements/Check List for Clinical Trials**
- Standard Operating Procedures for Obtaining Consent**
- Guidance re: Consent Forms and Sample Consent Form**
- Research Recruitment Advertising Guidelines**

General Submission Guide

- **All** submissions to the REB must include evidence of successful completion of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) Tutorial, a human protections course. The tutorial is available at: <http://www.pre.ethics.gc.ca/english/tutorial>.
- The course must be completed by each person working with subjects in the study (e.g., investigators, assistants, students, volunteers).
- The study investigators must sign all protocol forms and other communications to the REB. Similarly, all correspondence from the REB will be addressed to the principal investigator.

DEADLINES

- Deadlines for submission of new protocols: the first business day of each month.

CRITERIA FOR EXPEDITED REVIEW

- Although Toronto Academic Health Sciences Network (TAHSN) guidelines are broader, the CAMH Research Ethics Board (REB) will **consider** expedited review of **only** the following:
 1. Studies involving only chart reviews;
 2. Studies involving only secondary analysis;
 3. Studies already approved by another TAHSN, Research Ethics Board;
 4. Minor amendments to approved studies.
- **The full REB will review all other studies.**
- If you wish to apply for expedited review, please provide 2 copies of the full REB application materials.

CONTRACT REVIEW

- All contracts must be submitted to the CAMH Research Contracts Office (RCO) for review. **The REB also reviews contracts.** The RCO will submit the contracts directly to the REB. REB will send approval letters for the protocols and contracts.

APPROVALS

- Approvals are for 1 year only: to obtain continuing renewal, investigators must submit an “Annual Renewal of Ethics Approval” form.
- When a study has been completed or terminated, investigators must submit a “Final Report for the Research Ethics Board” form.

General Check List (Please check each box and attach completed check list to front of TAHSN Application)

- Completed checklist included with each copy of protocol form?
- All material collated?
- Current version of TAHSN protocol form - **completed in full?** (*Reference to another document will not suffice*).
- Consent form(s)?¹ If not, why not?
- If subjects are under age 16, assent form?
- If recruiting subjects by advertisement, copy of ad?²
- C.V.'s for all investigators? (electronic version).
- 3 copies of any grant **with budget?**
- If internally funded, 3 copies of budget?**
- All non-standard instruments to be used in the study.**
- Clear information re: all parties in the research, e.g., CRO's, other institutions?
- Are all signatures in place **with names printed below?** (All investigators' signatures are required; Director of Department signatures are required).
- If this is an investigator-initiated clinical trial?
- Does the principal investigator of the study have a primary appointment at CAMH?
- Is the research going to be conducted at CAMH?
- Does the research involve patients or clients of CAMH?
- Are any study funds being administered by CAMH?

¹ See pp. 40-41 "Guidance re: Consent Forms".

² See pp. 42-43, "Research Recruitment Advertising Guidelines".

CAMH staff, go to:

http://insite.camh.net/programsanddepartments/research/research_intranet/internal_forms_and_guidelines12376.html
(Research Recruitment Advertising Guidelines /Press Release Templates Style 1 & Style 2)

CHECKLIST FOR PROTOCOLS INVOLVING GENETIC SAMPLES

The following items should be addressed in the protocol submitted to the REB:

- *The rationale for taking genetic samples.*
- Confidentiality: are samples identified, anonymized, coded? If coded, who has the code?
- Where will samples be obtained?
- Where will samples be stored/banked and who will have access to them?
- For what period of time will samples be stored/banked?
- What are the procedures for disposal of samples?
- Is there provision for feedback of results to those who have donated the samples? If so, is genetic counseling available?
- *If the principal investigator of the study moves or retires, what happens to any stored samples?*
- If samples are to be shipped from an offsite location is there a contract in place to cover this? Does the contract include a Material Transfer Agreement?
- What are the consent arrangements in the study? Have subjects consented for use of their sample(s) for this study only (closed consent) or is consent broader and includes use of the samples in the future for similar studies or for research in general (open consent)? Does the consent form discuss any potential social risks of genetic testing, for example, loss of insurance coverage? Will subjects be contacted again? Does the consent form discuss providing results of genetic testing to the subject (and to his family)? Is it clear in the consent document what withdrawal from the study would mean, e.g. does it include withdrawal and destruction of the sample or complete anonymization of the sample and associated data?
- A clear statement in the protocol and consent form as to who can benefit from any commercial application from the samples: the study sponsor? the investigator? the study subject?

Check List for Clinical Drug Trials both Sponsor - and Investigator-Initiated

- What phase is this trial? Phase I or II or III or IV?
- Has a Clinical Trials Application (CTA) been submitted to Health Canada?
If no CTA has been submitted, what is the justification for this?
- Have you enclosed your Letter of No Objection? Yes.....No.....To follow.....
(Investigators are reminded that the REB will not give final approval to a clinical drug trial until the Letter of No Objection has been submitted.)
- If the submission involves an amendment, have you enclosed the approval letter from Health Canada citing the Control Number? Yes.....No.....To follow.....
(Investigators are reminded that the REB will not give final approval to a clinical drug trial amendment until the Control Number has been submitted.)
- For Sponsor-Initiated trials, have you enclosed 18 copies of the Sponsor Protocol?
- Have you submitted a copy of the Investigator's Brochure to the REB?
- Consent forms:³
 1. Must meet ICH/GCP requirements<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6_e.html#4.0>
(Section 4.8: Informed Consent of Trial Subjects);
 2. Must meet FDA requirements
<<http://www.fda.gov/oc/ohrt/irbs/appendixb.html>>
 3. Must refer, in the confidentiality section to access by Health Canada and the CAMH, Research Ethics Board;
 4. Must be initialed by the subject at the close of each page (in addition to being signed and dated at the form's conclusion);
 5. Must identify the Qualified Investigator and include his/her telephone number.

Please Note: See page 37, Consent Form Requirements/Check List for Clinical Trials.

Please Note: Clinical Trial Registration, see:

<http://insite.camh.net/programsanddepartments/research/researcher_resources13397.html>.

Please Note: Health Canada requires that study records for investigational drug or device trials be stored for 25 years, to be available for possible inspection.

³ See pp. 40-41, "Guidance re: Consent Forms".

Consent Form Requirements/Checklist for Clinical Trials
Please complete for every consent form being used

CONSENT AND CONTACT INFORMATION	
Name and phone number of Principal, Qualified and Co-investigators	
Person who may be contacted about research and phone number	
Subject has had opportunity to ask questions about study; has had them answered to their satisfaction	
Subject should sign and date consent form (also initial each page)	
Signed by person who obtained consent – Not as witness	
Contact for rights of trial subjects	
Subjects given copy of consent form	
SUBJECT EXPECTATIONS/BENEFITS/RISKS	
Statement that study involves research	
Brief step-by-step description of proposed research as experienced by subject (subject responsibilities)	
Distinguish between those interventions that are standard therapy and those that are research (research involves use of procedures not generally accepted – Treatment study)	
Inconveniences/discomforts to subject	
If harms a) probability of occurrence b) clinical importance of harm c) probability of reversibility	
Reasonably foreseeable risks	
Benefits to subject	
If others will benefit (society/people with similar conditions)	
Expected duration of subjects participation in trial	
If subject receiving therapy prior to enrollment explanation that therapy may be altered/discontinued as part of study	
Probability for random assignment to each option	
Explanation of invasive procedures (e.g. amount of blood taken; radiation exposure)	
Approximate number of subjects involved in trial	
Explanation of outcomes from not participating in study (Treatment study)	
If treatment alternatives are available (Treatment Study)	
PRIVACY AND ACCESS TO INFORMATION	
Review of patient's health record	
Subject will be informed in a timely manner of any new information/changes to study that may effect willingness to participate (re-consented)	
Anticipated secondary use of data (if any)	
Limit on the use, retention and disclosure of data	
Confidentiality respected to extent of law	
Subject identity remains confidential (in publications)	
Statement CAMH monitor/Health Canada may access files	
RULES FOR PARTICIPATION	
Reimbursement for participating (pro-rated for withdrawing)	
Participation is voluntary, can withdraw at any time	
Outcomes of withdrawing from study (if any)	
Circumstances/reasons that Subject participation may be terminated	
Outcome of termination of participation in study (if any)	
CONFLICT	
Signing consent doesn't waive subject's legal rights nor relieve investigator/sponsor/institution from legal responsibility	
The compensation and/or treatment available to the subject in the event of trial-related injury	
Name of sponsor	
Any conflict of interest a) identity of person with competing interest b) type of incentive/inducement c) source	

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

1. Obtaining consent for research is a continuing process.
2. The consent form/information sheet is simply a record of the process that has occurred between the prospective research subject and the person obtaining consent.
3. Those who have a treating relationship with the prospective subject must not obtain consent. Instead, the patient can be asked for permission for someone without a treating relationship to approach him/her to discuss the study.
4. The discussion of the study should take place in a quiet place where confidentiality can be protected.
5. The study should be described in simple terms and examples given where possible and appropriate.
6. All questions should be answered.
7. Prospective subjects should be encouraged to take the consent document home with them for further consideration and discussion with appropriate others (e.g. family members, family physician).
8. Ample time should be allowed for the prospective subject to decide whether or not to participate in the study.
9. Only consent documents approved by the Research Ethics Board (REB) should be used. Where a number of versions of the form exist, the current one must be used.
10. When the consent form is signed, the subject should review each page and initial it.
11. In certain situations (for example when enrolling subjects who are illegal drug users and may want complete anonymity) it may be possible to use an information sheet only and not a signed consent form. In these circumstances the other aspects of the consent procedure should still be observed.
12. 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.
13. If there is doubt about an individual's competency to provide fully informed consent, a competency assessment should be performed by a psychiatrist who is not associated with the study.
14. On occasion, the REB may approve a research protocol that proposes to use third party consent, (for example, consent of the next-of-kin). These situations are usually limited to protocols in which it is shown that the study cannot be conducted with a consenting population and in which there is potential benefit to the subject.
15. Subjects under age 16 years of age should be given an assent form containing a simplified version of consent information. In addition, parental consent is required.
16. When consent has been obtained, the subject should receive a copy of the form to keep.
17. In studies in which a medical record is kept, a copy of the consent should be put into the record.
18. The study investigator should retain the original consent form.
19. Since consent is a continuing process, subjects should be encouraged to ask questions and/or state concerns as their participation in the study progresses.

Guidance re: Consent Forms

- If the study involves positron emission tomography (PET), refer to the “PET Centre Guidelines for Informed Consent Statements”, available at CAMH website: http://www.camh.net/Research/research_ethics/protocol_forms_guidelines.html.
- Consent forms should be written in lay language at an approximate grade 6-8 reading level.
- **Consents should be written in the second person.**
- While the information in the consent form should be written in the second person, there should be a statement at the end of the consent form for the participant to sign agreeing to participate, and this should be in the **first** person.
- The form should be placed on the institutional **letterhead** and broken into point form.
- Terms like “randomization”, “double-blind” and “placebo” should be explained in lay language.
- Consents should give the **study title** at the top of the form.
- Consents should name the **investigators** after the title.
- Consents should name the **sponsor** also.
- At the end of the form there should be **contact names for questions**: i.e., the investigators; and contact names for questions about subject's rights.
- “Dr. Pdraig Darby, Chair, Research Ethics Board, Centre for Addiction and Mental Health, may be contacted by research subjects to discuss their rights. **Dr. Darby may be reached by telephone at 416-535-8501 ext. 6876.**” This information should be included on all CAMH consent forms.
- Initially a statement should be included that the individual is being asked to participate in research and why it is they are being asked.
- A comprehensible statement of the research purpose, identity of the researcher, the expected duration and nature of participation and a description of the research procedures; (only procedures which are being done specifically for the research need to be described).
- Early in the form a statement should be included concerning alternatives to participation - i.e. what would be considered standard treatment for the condition being investigated.
- A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action should be given.
- An assurance that the prospective subjects are free not to participate and have the right to withdraw at any time without affecting the quality of their care.
- 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.
- An indication as to who will have access to information collected on the identity of subjects and descriptions of how confidentiality will be protected;
- in the Confidentiality section of the form, subjects should be advised that their study files may be reviewed by the REB.
- A statement about any payment to subjects and whether or not it will be prorated. **Specific dollar amount of payment to subjects may be listed in the consent, but NOT in any advertisement.**
- The name and telephone number of the principal investigator.

- The name and telephone number of an additional contact person (who is not involved in the study) to whom participants can direct questions. **This information should be included on all CAMH consent forms.**
- The approximate number of participants in the trial and whether the study is multi-centred.
- In addition, please consider the following:
 - 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.
 - Similarly, if you think you may wish to use data from the study for future research please provide subjects with as much information as possible about future data use; i.e., the type of research and any protections of subject confidentiality and the like.
 - Any taping must be addressed in the consent form.

For studies involving children, parental consent is required for those under age 16. ***Please attach a copy of the proposed consent form(s) and any information sheets and/or letters to the subjects to your protocol form.***

SAMPLE CONSENT FORM

- Investigators are reminded that more study approvals are delayed because of the need to make consent form changes than for any other reason.
- A sample of an appropriate consent form is attached with the permission of the study investigators.
- **Consent forms should be initialed on each page, by the subject, to demonstrate that they have read that page of the document.** The subject should then sign the form in the usual manner.
- Consent forms should include the following statement:

Consent forms must include the following statement: "As part of continuing review of the research, your study records may be assessed on behalf of the Research Ethics Board. A person from the research ethics team may contact you (if your contact information is available) to ask you questions about the research study and your consent to participate. The person assessing your file or contacting you must maintain your confidentiality to the extent permitted by law.

Where the study is under the authority of Health Canada (for example, it involves evaluating a new drug) consent forms must also include the following statement: *"This study is under the authority of Health Canada as it, for example, involves evaluating a new drug. Your records may therefore be assessed by the Health Canada Therapeutic Products Programme."*

- Guidance re: Consent Forms can be found in this Handbook on pages 37-39.

2. You will be asked some questions about your smoking habits.
3. You will be given either the drug or placebo syrup, followed by a light breakfast. Testing will begin 90 minutes after you consume the syrup. A newspaper and magazines will be available for you to read while you wait for testing to start.
4. At the start of testing we will repeat the measurements described in (1).
5. Next you will complete several tasks on two different computers. Some are questions for you to answer, and others ask you to respond quickly to certain cues. The tasks will be explained to you. They are straightforward to do, are not intended to make you feel ill-at-ease, and you may find some of them interesting.
6. You will smoke one of your own cigarettes. When you smoke the cigarette, it will be inserted in a holder connected by tubing to an instrument that allows us to measure how many puffs you take, and the size of those puffs. You will smoke this cigarette as you would normally smoke.
7. When you have finished smoking the cigarette, we will again repeat the tests in (1) and the tasks in (5).

After the completion of the study, we will explain to you why we do the various parts of it. We will ask you to remain at the Centre for Addiction and Mental Health until we believe that it is safe for you to leave, that is, until the effect of the drug has worn off sufficiently. You should not drive a motor vehicle, or operate machinery, for the rest of the study day. We will give you a card that shows a contact number at the Centre for Addiction and Mental Health in case of an emergency related to the study.

Eligibility: To participate in this study you must be male, between the ages of 19 and 45 years old, and currently smoke at least 15 cigarettes per day. You must not have participated in other parts of this study. You may not participate in this study if you are taking any medications. You are also not eligible if you have a psychiatric illness, heart disease or asthma.

Confidentiality: Your identity will be kept confidential to the full extent provided by law. In addition, neither your name nor any other personal identifier will be used in any reports or publications arising from this study. As part of continuing review of the research, your study records may be assessed on behalf of the Research Ethics Board and, if applicable, by the Health Canada Therapeutic Products Programme. A person from the research ethics team may contact you (if your contact information is available) to ask you questions about the research study and your consent to participate. The person assessing your file or contacting you must maintain your confidentiality to the extent permitted by law.

Subject's Initials:

Compensation: You will receive \$100.00 to compensate you for your time (\$20 if you complete the health screen only; \$80 for the test day). Payment for partial participation on the test day will be pro-rated on an hourly basis. We will provide transit fare for you to get to and from the Centre on the days of the health screen and the study.

Risks: Abstinence from nicotine may cause you to have some mild discomfort. The drug chlorpromazine may cause you to feel mildly unwell or unhappy. If this happens, the effect will be short-lasting, several hours at most. Taking the blood sample may cause temporary pain and/or bruising, and there is a small risk of infection from this procedure.

Benefits: This study has not been planned to help you stop smoking now, but it may provide information that will be useful to help people stop in the future.

Voluntary Participation: Your participation in this study is voluntary. You may choose to withdraw from the study at any time. In addition, the investigators or their staff responsible for this study may, at their discretion, end your participation at any time. If your participation ends early for whatever reason, you will be compensated on a pro-rated basis as described above. Your choice to not participate, your choice to withdraw, or your dismissal by us will not affect any treatment needs that you might have at the Centre for Addiction and Mental Health now or in the future.

Additional Information: If you have questions about the study that are not answered in these Information Sheets, please ask them. In addition, if you have questions in the future you may contact the study investigators at the telephone numbers given on the first page. Dr. Padraig Darby, Chair, Research Ethics Board, Centre for Addiction and Mental Health, may be contacted by research subjects to discuss their rights. **Dr. Darby may be reached by telephone at 416-535-8501 ext. 6876.**

Subject's Initials:

AGREEMENT TO PARTICIPATE

I, _____, have read (or had read to me) the Information Sheet for the study named 'Reactivity to smoking cues in nicotine dependent smokers.' The purpose of this study is not to help me quit smoking. My role in the study is as a research volunteer to help the investigators collect information about the effects of smoking. This information may or may not be useful in designing better ways to help people quit smoking in the future. My questions, if any, have been answered to my satisfaction. By signing this consent form I do not waive any of my rights.

Dr. Pdraig Darby, Chair, Research Ethics Board, Centre for Addiction and Mental Health, may be contacted by research subjects to discuss their rights. **Dr. Darby may be reached by telephone at 416-535-8501 ext. 6876.**

I agree to participate.

Research Volunteer:

Signature: _____

Date: _____

Name: _____

Please Print

Person Obtaining Consent:

Signature: _____

Date: _____

Name: _____

Please Print

I have been given a copy of this form to keep.

RESEARCH RECRUITMENT ADVERTISING

AD APPROVAL

All research recruitment advertising needs to be approved by Research Communications before it can be posted. Once you have received CAMH REB approval, a copy of your ad will be sent to Research Communications for review. Before you proceed with posting your ad, either on the Research Bulletin Boards or through Public Affairs, please contact Polly Thompson, Manager, Research Communication:

Room T114, RS site
by email at: polly_thompson@camh.net
or ext. 4932

GUIDELINES FOR RESEARCH RECRUITMENT ADVERTISEMENTS

- It's important that all research advertisements send an appropriate and consistent message about CAMH. The ads should reflect CAMH, its work, and its vision, mission and values.
- Please ensure that your research ad complies with the following guidelines:
- The research recruitment message must be the first message in the ad so that the ad is not misinterpreted as a public awareness ad or treatment announcement.
- The ad must clearly and strongly state that interested individuals will need to qualify for the research study in order to participate.
- The ad must include the CAMH logo, and indicate how the public can find out about treatment options available by including the tagline "For more information about programs and services at CAMH please visit <http://www.camh.net/or call 416-535-8501> (or 1-800-463-6273)"
- Please ensure appropriate language is being used in the advertisement – specifically please avoid using language that may reinforce the stigma and public misconceptions about mental illness and addiction.
- Refer to the CAMH sites as:
 - o Russell Street site (not ARF site)
 - o College Street site (not Clarke site)
 - o Queen Street site
 - o Brentcliffe Road site (not Donwood site)

ADVERTISING TEMPLATES

Advertising templates (http://insite.camh.net/files/recruitment_ad_template_1.doc or http://insite.camh.net/files/recruitment_ad_template_2.doc - referred to as “Research Recruitment Advertising templates”) have been developed that include the CAMH and U of T logos as well as the tagline.

TELEVISION ADVERTISING

Special consideration should be given to developing television ads for research subject recruitment. If television ads are being considered for research recruitment, please contact **Public Affairs** in the initial stages to ensure consistency, and facilitate access to CAMH’s stock footage and images and other audiovisual resources.

RESEARCH RECRUITMENT AD POSTING PROCESS

Researchers are responsible for their posting and maintaining their own ads on the internal research posting boards – all postings must have the “public affairs approval” stamp on them prior to posting.

LOCATIONS OF RESEARCH BULLETIN BOARDS:

Location	Number of Posting Sites	Description
Brentcliffe Road site	1	Current display areas
Russell Street site	2	Outside the cafeteria (2 nd floor, west side) and lobby of the Spadina Avenue entrance
Queen Street site	1	Cafeteria
College Street site	2	Main floor outside the auditorium, and front lobby on the ramp from the front lobby to the elevators

***The Research department will monitor these bulletin boards (see list above) – all ads posted without approval stamp or ads that are not CAMH research study ads will be removed.**

Research recruitment flyers can also be displayed on the designated CAMH public bulletin boards/display areas, by submitting 42 copies of the flyer to Public Affairs as per the posting policy.

If you have any questions or comments, please feel free to contact Director of Research Operations (ext.4745) or Polly Thompson – Manager, Research Communications (ext.4932).