

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.