

GUIDELINES FOR PRINCIPAL INVESTIGATOR-CONSENT FORM

The investigator must complete, sign, and submit to the Research Review Committee ("Committee") this form with any consent form intended for use in obtaining informed consent¹ from individuals participating in the proposed research study.

Title of Study:

Principal Investigator(s):

SECTION I - General Information

Summarized below are the requirements for written informed consent which are applicable to all research. The content of the written consent form and the manner in which such consent will be sought is part of the Committee's review of the research proposal. With regard to research projects that involve only access to private information, an exception to the requirement of a written consent form may apply (see SECTION III.B. for specific details).

The consent form must be written in language understandable to the subject and to the guardian, if applicable. In general, consent forms should be written in lay terms that a person with reading ability at the sixth grade level will understand. Also, the consent form should be in a written narrative format and written entirely in first person singular tense. The form must not include any waiver of the participant's rights or include any exculpatory language absolving the investigator, the sponsor, the Department of Developmental Services, the program or their agents from liability for negligence. Consent forms should be two-sided if over one page in length so that signatures are not separated from the text. Alternatively, each page must be initialed and dated by the prospective participant. A copy of the consent form, as approved by the Committee, must be given to each research participant and his or her guardian², if applicable. If a clinical record exists, the PI must insure a copy is filed in that record. The Committee may require a witness to be present at the time consent is sought. In cases where the participant is presumed competent to give informed consent, a witness who is knowledgeable about the prospective participants abilities must also sign the consent form attesting to the fact the individual understands the contents and intent of the form and is able give informed consent. Notwithstanding the consent of the guardian, an individual's participation in a research project must nevertheless cease if the individual objects, by verbal or nonverbal means, to participation.

1. "Informed Consent" means the knowing consent voluntarily given by a participant (or if the participant is legally incompetent, by his guardian, if applicable) who can understand and weigh the risks and benefits of the proposed research for the participant.

2. "Guardian" means with respect to persons under the age of eighteen (18) years, a natural or adoptive parent, or the individual or agency with legal guardianship of the person; and with respect to persons eighteen (18) years of age and older, the individual, organization or agency, if any, that has been appointed legal guardian of the person found to be incompetent by a court of competent jurisdiction. If a guardianship has been limited in any way by the court, the guardian's informed consent must be obtained only in those cases where a decision regarding participation in the research falls within the scope of the limited guardianship.

SECTION II - Consent Form Contents Checklist

The consent form must provide to each participant in the research study the following minimum information:

- (1) A statement that the study involves research, what is expected of the participant, with a full explanation of the purposes and objectives of the research. (See SECTION III.A. for application of a modified consent procedure where the research involves minimal or no risk and a full explanation of the purposes and objectives of the research to the participant would compromise or invalidate the study.)
- (2) The basis for selection of the participant.
- (3) The expected duration of the individual's participation in the study.
- (4) A description of the procedures to be followed and the identification of any procedures which are experimental.
- (5) A description of any reasonably foreseeable risks or discomforts to the participant, their expected severity and duration;
- (6) A description of any benefits to the participant or to others which may reasonably be expected from the research.
- (7) A statement describing how the confidentiality of records and the privacy of participants in the study will be maintained.
- (8) A description of any appropriate alternative procedures or courses of treatment that could be used in lieu of the experimental procedure, or if there is no alternative procedure;
- (9) An offer to answer any questions concerning the procedures and the participant's rights.
- (10) A statement indicating whom to contact and how to do so for further information.
- (11) A statement that participation is voluntary and the individual is free to withhold consent or to withdraw consent and to discontinue participation in the research at any time without penalty or loss of benefits otherwise being received.
- (12) If the prospective participant is an individual receiving services provided or purchased by the Department or a family member of such an individual, a statement that mental retardation services to the individual do not depend on participation by the individual or family member in the research.
- (13) Where applicable, a description of any controlled substance as defined in the Massachusetts Department of Public Health regulations implementing G.L. c.94, and any other substances to be used, and their anticipated effects, side effects and interactions. The description must be in language understandable to the prospective participant or guardian.

SECTION III Modified Consent Procedure and Exception

A. Modified Consent Procedure

The Committee may approve a modified consent form (as outlined under SECTION III.C.), but only if it finds and documents that all of the following conditions listed are met:

- (1) The proposed research involves no more than minimal risk of social, psychological, or physical harm to the participant;
- (2) A full explanation of the purpose(s) or objective(s) of the research before its completion would compromise or invalidate the study;
- (3) The consent form provides the following information to each prospective participant and their guardian, if applicable:
 - (a) a statement that the study involves research;
 - (b) a general description of the nature of the research;
 - (c) a statement that some aspects of the research purpose(s) or objectives are being withheld from the participant;
 - (d) a statement that after the individual's participation in the research, the individual will be provided a written full explanation of the research purpose(s) and objective(s);
 - (e) a statement that the individual agrees to participate in the research in the absence of a full explanation of the purpose(s) and objective(s) of the research study.

B. Exception to Consent Form Requirement

The Research Review Committee may approve a research proposal (as outlined under SECTION III.C.) without written consent under the following conditions:

- (1) the research consists of the study of historical records, and the researcher presents to the Committee plans designed to protect the confidentiality of the information and to preclude the identification of particular individuals; or,
- (2) the research consists of a review of records for the sole purpose of extracting information for a demographic or statistical study in which no person can be identified.

C. Procedure

Where a research investigator wishes to utilize the modified consent procedure or exception described under paragraphs A and B, the investigator must submit to the Committee, as part of the research proposal submission, specific and detailed reasons for seeking such consent procedure or exception. The Committee may impose such conditions as it deems appropriate to safeguard the rights and welfare of the participants. Such conditions may include the appointment of advocates and monitors and stringent procedures to protect the confidentiality of personal information.

Signature of Principal Investigator(s)

Date