

Human Subjects in Research

Policy

Loyola Marymount University

October 2008

**POLICY ON THE USE OF HUMAN SUBJECTS
IN RESEARCH**

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1. Institutional Review Board (IRB) 2008-2009

Member Name	Earned Degrees	Primary Scientific or Nonscientific Specialty	Comments
Dr. Stacy Burns	M.A., J.D., Ph.D.	Scientific	Associate Professor of Sociology and Chairperson of Department
Dr. Martin T. Connell, S.J.	M.A., M.Div., Ph.D.	Scientific	Assistant Professor of Education
Dr. David J. Hardy	M.A., Ph.D.	Scientific	Assistant Professor of Psychology
Dr. Nicholas Kockler	M.S., Ph.D.	Scientific	Professor of Bioethics
Dr. James Konow	M.A., Ph.D.	Scientific	Professor of Economics and Chairperson of the Department
Dr. Debra Linesch	M.A., Ph.D.	Nonscientific	Professor of Marital and Family Therapy and Chairperson of the Department
Ms. Jean Pennicooke	M.A., CSUDH Administrative Credential	Nonscientific; External Unaffiliated Member	Educator, Principal of Kentwood Elementary School, LAUSD, External unaffiliated Member
Mr. David A. Ramirez	A.T.C., M.A., C.S. C.S.	Scientific	Assistant Professor of Natural Science
Dr. Abhik Roy	LL.B., M.S., Ph.D.	Nonscientific	Professor of Communication Studies and Chairperson of the Department
Dr. John Carfora	M.A., Ed.M., Ed.D	Nonscientific	Chair, LMU IRB Committee, Executive Director of Sponsored Research, Sponsored Projects Office

2. Specific Federal Regulations and Policies

[HHS](#) [Protection of Human Subjects](#) (45 CFR Part 46)

FDA FDA - [Protection of Human Subjects](#) (21 CFR Part 50)

[Institutional Review Boards](#) (21 CFR Part 56)

A. Related Guidance and Other Resources

The Belmont Report - [Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#)

[Expedited Research and Research That May Undergo Expedited Review](#) (from the old OPRR Reports)

Informed Consent Checklist - [Basic and Additional Elements](#)

OHRP - [Home Page](#)

OHRP - [Procedures for Registering Institutional Review Boards and Filing Federalwide Assurances of Protection for Human Subjects \(FWAs\)](#)

OHRP - [Summary of Basic Protections for Human Subjects](#)

Public Responsibility in Medicine and Research (PRIM&R) - [Human Subjects Research Tips on Informed Consent](#)

3. Introduction

Loyola Marymount University is committed to a policy of safeguarding the rights and welfare of all human subjects in research. The university accepts the principles set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in its report, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (commonly known as the Belmont Report). The commitment to these principles includes recognition of **necessity for review of a research project independent of the investigator** to ensure optimum protection of human subjects involved in that project. However, this commitment extends beyond the requirements of federal regulations and is not affected by the sources of research funding.

Three basic ethical principles cited in the Belmont Report (available upon request) are:

- **Respect for Persons.** Human subjects must be treated as autonomous and able to make responsible choices. This principle leads to the requirement of informed voluntary consent.
- **Beneficence.** Subjects must be protected from harm and their well being must be secured. This principle leads to the requirement that the benefits to subjects or to humanity generally must be judged to outweigh the risks to subjects.
- **Justice.** The risks and benefits of research must be distributed fairly without creating differences in treatment among ethnic, racial, religious, sexual, or age defined classes. This principle leads to the requirement that investigators take care not to exploit special categories of persons less able to refuse participation in research such as prisoners, mental patients, and children.

Applications of these principles lead to the standard expectations that investigators will:

- Secure informed consent by (a) making real efforts to see that subjects understand the project, (b) providing "a way out" for subjects if they desire one, and (c) providing a way for questions to be answered.
- Systematically evaluate risks and benefits of their research.
- Select subjects in a fair manner that does not exploit some especially vulnerable category of people.

4. Campus Guidelines

These guidelines are issued by the LMU Institutional Review Board to inform investigators of LMU's policies for the protection of human subjects and to help researchers prepare their applications for review and approval of research by the Institutional Review Board (IRB).

The primary function of the IRB is to ensure that the legal and ethical rights of research subjects are safeguarded. One of these ethical rights is to have trust that participation in a research project will result in useful data. In the course of reviewing submissions to the IRB, committee members may note minor or serious flaws in the proposed protocols that may compromise the integrity of the study. Individuals submitting proposals to the IRB are reminded that in order to be reviewed, applications must be complete and all necessary documentation provided. The IRB recommends that the proposal be pre-reviewed by individuals knowledgeable in the experimental designs and statistical analyses to be employed. Graduate and undergraduate students, especially, should have their advisors or thesis committees review the protocols prior to submission. If the IRB deems a proposal to suffer from serious design flaws, the proposal will be returned and not be reviewed.

All investigators should carefully read these guidelines. All principal investigators (faculty, students, and staff) must supply the IRB with the information relevant to their proposed research. Careful attention to detail will shorten the review process. Please note that these forms are periodically revised to reflect changes in federal regulations, state laws, and University policy.

Based upon Title 45, Code of Federal Regulations Part 46–Protection of Human Subjects – **research involving human subjects conducted by or under the direction of LMU investigator, using any property or facility of the University, funded or not, regardless of location, must be submitted to the IRB for review and approval.** Research proposals must be approved by the IRB prior to the initiation of any activity and the research may not continue past its approved term. In no case can the IRB approve a protocol for a period longer than one year and under no circumstances can retroactive approval be granted. If a principal investigator has, or should have, knowledge of the applicable University policy requiring that every research activity placing human subjects at risk be reviewed by an IRB and fails to obtain such approval prior to involvement of human subjects, the investigator would be actually outside the scope of his/her duties and University would not be obligated to defend or indemnify the investigator if legal actions were initiated by a subject.

The IRB holds to itself the right and obligation to inform itself on all aspects of a proposed research activity. As a part of its review process, the Committee may seek counsel, advice, or verification from sources other than the investigator, including consultants, and may request demonstration of all or part of a proposed research activity.

Exempted categories of research involving a human subject are specified by 46.101(b)1-6 of the Revised Regulations dated March 8, 1993, and are included in this booklet. Such studies involve the use of educational tests, survey or interview procedures, observation of public behavior, or utilization of publicly available sources of information under certain conditions. These categories are published on the statement of exemption form (included). Please note that some of the exemptions do not apply to research studies involving minors.

5. Commonly Used Definitions

Research: a systematic investigation designed to develop or contribute to generalized knowledge. (45CFR46)

Clinical investigation: any experiment that involves a test article (investigational new drug or device) and one or more human subjects. (21CFR50)

Test article: any drug, including a biological product, or medical device for human use. (21CFR50)

Medical experiment: the severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of such subject or otherwise directly benefiting such subject; the investigational use of a drug or device; withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of such subject. (Ch.1.3, Division 20 of the California Health and Safety Code.)

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information. (45CFR46)

Minimal Risk: risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45CFR46)

New Submission: the first time application for approval of a research project.

Continuation Submission: an application for extension of approval for an ongoing research project.

Renewal Submission: for ongoing extramurally funded projects, an application for extension of approval beyond the originally awarded grant/contract period; for ongoing unfunded projects, an application for extension of approval after 4 years of continued approval.

Addendum: an application for approval of changes to the protocol and/or informed consent form within the approval period of a project; application seeking additional funding for a project identical to an ongoing study approved by the IRB.

6. Confidentiality

Material submitted to the IRB should not contain any personal information on subjects that make them identifiable.

Principal investigators should be aware that the disclosure of Social Security numbers by subjects is voluntary except where the number is required by law.

7. Injuries to Subjects

The IRB must be notified immediately of any injuries to human subjects resulting from participation in a research activity and any unanticipated problems that involve risks to the human subjects or to others.

8. Informed Consent

In most studies involving human subjects informed consent must be obtained and any explanation, whether in written or oral format, must be given in the language of the subject by a person competent in the area of the proposed research. If the natural language of the subject is not English, and these subjects are poorly versed in English language, an appropriate translation of the approved Informed Consent Form(s) must be provided to subjects.

The principal investigator must submit a specific informed consent form or forms. For research projects where only verbal consent is contemplated, a script for any oral explanation to be given to subject(s) must be developed. (Requests for omission of signed informed consent or modification of any basic element of informed consent must be fully justified.) Otherwise, a clear, legible consent form written in simple lay terms must be written. The language of the consent form should not make it appear that the subject is made to waive, or appear to waive, any of his/her legal rights.

Only approved informed consent forms can be used. Consent forms shall be written in the FIRST PERSON and must contain all the points covered in Guidelines to Informed Consent contained in this booklet. Sample wordings are provided in the Sample Informed Consent Form.

Principal Investigators are hereby advised that signed informed consent forms are institutional records, **shall be retained for at least five years** after termination of the last IRB approval, and shall be accessible for purposes of audit.

9. Joint Application Submissions

When work is carried out jointly between a LMU principal or co-principal investigator and an investigator from another institution, and IRB approval has been previously obtained from that institution, a copy of that institution's approval must be submitted as part of the LMU application.

10. New and Renewal IRB Application Requirements

All new and renewal applications, which involves human subjects should be approved by the IRB. Renewal submissions should consist of the same information as new submissions, including a specific answer to #7 on the New Submissions Questionnaire. Renewal submissions must be processed in the same way, with approval notices filed appropriately with LMU's IRB.

For your convenience, the IRB Application can be completed using Microsoft Word.

All new and renewal submissions should contain:

1. A completed and signed full IRB Application form. - indicate on application if it is a NEW, RENEWAL, or an ADDENDUM (Please provide IRB number if previously assigned one);
2. A research protocol (i.e., description of the purpose and methodology of the research procedures) plus any supporting materials;
3. Informed Consent Form(s) developed in accordance with the IRB guidelines;

A copy of the **Completion Certificate** from the NIH Office of Extramural Research website. This is a free 2 hour on-line tutorial that is required of all faculty and student applicants, as well as student faculty advisors, conducting research and surveys that involve human subjects. The Completion Certificate can be accessed by clicking on the link below or typing it on your URL tab or your browser, <http://phrp.nihtraining.com/users/login.php>

4. and a copy of the Grant Application if research is extramurally funded.

If assistance is needed in the preparation of your materials, please contact the Chair's office at ext. 4599.

11. Exemption from Full IRB Review

If you believe that your project qualifies for Exemption from Full IRB Review, you must fill out an Application for Exemption form, cite the number(s) from the list of Exemption Categories and briefly describe each category as applicable to your project.

All applications for exemption must include the following:

- A one to two page research protocol description of the study (rationale, supporting literature, and summary of the method) plus any supporting materials.
- A copy of the Completion Certificate from the NIH website.

- A brief description of what you plan to do with the research results.

You should allow at least four weeks for the review process. Incomplete applications will be returned. Inadequate response will lead to delay of review.

11. New IRB Application Questionnaire

1. SUBJECT RECRUITMENT

How will subjects be selected? What is the sex and age range of the subjects? Approximately how many subjects will be studied?

How will subjects be contacted? Who will make initial contact with subjects? Specifically, what will subjects be told in initial contact?

2. PROCEDURES

Summarize fully all procedures to be conducted with human subjects.

3. RISKS / BENEFITS

What are the potential benefits to subjects and/or to others?

What are the reasonably foreseeable risks to the subjects? (Risks may include discomfort, embarrassment, nervousness, invasion of privacy, etc.) If there are potential risks to subjects, how will they be minimized in advance? How will problems be handled if they occur?

4. CONFIDENTIALITY

Will subjects be identifiable by name or other means? If subjects will be identifiable, explain the procedures that will be used for collecting, processing, and storing data. Who will have access to data? What will be done with the data when the study is completed?

5. INFORMED CONSENT

Attach an informed consent form or a written request for waiver of an informed consent form. Include waiver of written consent if appropriate. If your research is being conducted in another language, please include copies of the translated "Informed Consent" and "Waiver of Written Consent" forms.

6. STUDENT INVOLVED RESEARCH

When a student acts as principal investigator, a faculty sponsor signature is required on the application form.

7. RENEWAL APPLICATIONS

When the submission is a Renewal Application, include a summary of the research activities during the previous granting period specifically addressing the following: number of subjects studied and any adverse reactions encountered; benefits which have been derived; any difficulty in obtaining subjects or in obtaining informed consent; and approximate number of subjects required to complete the study.

8. If subjects will be screened, describe criteria and procedures.

9. If subjects are to be paid in cash, services, or benefits, include the specific amount, degree, and basis of remuneration.

10. When students from the Psychology Subject Pool (PSP) are involved as subjects, permission must be obtained from the PSP prior to running subjects.

Forms are available from the Psychology Office in Seaver Hall. It is not necessary to inform the IRB of approval from the PSP, however the PSP requires IRB approval prior to permission for using the pool being granted.

11. Describe the qualifications of or method of training and supervision afforded student experimenters.

12. Describe criteria for assigning subjects to sub-groups.

Such as control and experimental.

13. If the project involves deception, describe the debriefing procedures that will be used.

Include, verbatim, the following statement in the consent form: "Some of the information with which I will be provided may be ambiguous or inaccurate. However, the investigator will inform me of any inaccuracies following my participation in this study."

14. Include copies of questionnaires or survey instruments with the application (draft form is acceptable).

If not yet developed, please so indicate and provide the Committee with an outline of the general topics that will be covered. Also, when the questionnaire or interview schedule has been compiled, it must be submitted to the Committee for separate review and approval. These instruments must be submitted for approval prior to their use.

15. **To insure that all patients receive coordinated care, the principal investigator is obligated to inform the primary physician (when not the principal investigator) of all studies on his/her patients.**
16. **Describe provisions, if appropriate, to monitor the research data collected to insure continued safety to subjects.**
17. **To minimize risks to subjects, whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes. Describe provisions.**
18. **In projects dealing with sensitive topics (e.g., depression, abortion, intimate relationships, etc.) appropriate follow-up counseling services must be made available to which subjects might be referred.**

The IRB should be notified of these services and how they will be made available to subjects.
19. **When a research project involves the study of behaviors that are considered criminal or socially deviant (i.e., alcohol or drug use) special care should be taken to protect the identities of participating subjects.**

In certain instances, principal investigators may apply for "Confidentiality Certificates" from the Department of Health and Human Services or for "Grants of Confidentiality" from the Department of Justice.
20. **If advertisements for subjects are to be used, attach a copy and identify the medium of display.**
21. **When research takes place in a foreign culture, the investigator must consider the ethical principles of that culture in addition to the principles listed above.**

12. Waiver of Written Informed Consent

The signed informed consent process (i.e., a printed/typed informed consent form requiring the subject's signature) may be waived for some research projects in which either of the following conditions applies:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
- The research presents no more than minimal risk of harm to subjects and involves no procedure for which written consent is normally required outside of the research context.

Requests for waiver of a written informed consent form must be made in writing to the Board (see Waiver of Informed Consent) and include a statement citing which of the above conditions applies to the study in the opinion of the principal investigator. In any case, the Institutional Review Board holds the final determination of whether or not a written informed consent form is necessary for any individual research project. In cases where the documentation requirement is waived, the Committee may require the investigator to provide the subjects with a written statement regarding the research.

13. Preparation of Informed Consent Forms

Your Informed Consent Form should address each of the following points if applicable (see sample Consent form for examples of wording)

1. Identify by name, title, and degree, the person(s) responsible for and/or conducting the procedure(s). If the research project involves minors, the consent form should be written using "I (my child/ward)" throughout, using the proper verb tense and pronouns, allowing for statements to be read from the standpoint of the minor as subject, or the parent/guardian giving consent.
2. State the fact that the study is a RESEARCH project, the PURPOSE of the research, and HOW LONG the study will last.
3. State the reason WHY the subject has been selected.
4. In PLAIN LANGUAGE describe clearly the PROCEDURES or investigations (separating those which are research from those that are standard routine therapy) in which the subject will be involved and what is expected of the subject. The consent form must be written in simple lay terms. (Consider using sixth grade English.)
5. State, if applicable, that AUDIO/VIDEO TAPING or still photography are procedures in the study. Define permitted usages and detail the disposition of such material at the end of the study.
6. Provide in lay terms a description of the reasonably foreseeable immediate and long term DISCOMFORTS, HAZARDS, AND RISKS (physical, psychological, and/or social) and their potential consequences; if none, so state. In addition, patients/subjects must be informed that their condition may become worse despite participation.
7. Provide in lay terms a description of any potential BENEFITS OR VALUES that might reasonably result from the research. Identify those to be gained by the individual subject as well as those by society in general. If the individual subject will receive NO DIRECT BENEFIT, this must be explicitly stated.
8. For patients/subjects provide appropriate ALTERNATIVE PROCEDURES or drugs that might be advantageous.
9. If a CELL LINE is to be developed, include this statement verbatim. This must be initiated by consenting subject.
10. Identify the individual(s) performing and/or responsible for the procedure(s), their degree and where they may be reached (full address and telephone number) on a 24-hour basis. In addition, include a statement that questions will be answered at any time.
11. Include this statement **verbatim**: "If the study design or the use of the information is to be changed, I will be so informed and my consent reobtained."
12. All consent forms must provide a statement that the subjects are FREE TO WITHDRAW their consent and to discontinue participation in the project at any time without prejudice.

13. Include this statement **verbatim**: "I understand that circumstances may arise which might cause the investigator to terminate my participation before the completion of the study."
14. If any information derived from the research project can be used to personally identify the research subjects, statement #14 of the consent form must be used **verbatim**.
15. If the research holds a Certificate of Confidentiality, #15 of the consent form must be used **verbatim**.
16. If the research project involves use of questionnaires, subjects must be informed that they have the right to refuse to answer any question.
17. If the research project involves the use of **DECEPTION**, statement #17 of the consent form must be included verbatim. In addition, subjects must be informed that they will be debriefed after their participation.
18. If subjects are to be PAID, specify dollar amount and address the matter of PRORATION if the subject withdraws or if the investigator terminates the study.
19. Address, if applicable, charges that may be incurred by subject and/or insurance carrier.
20. If the research involves an experimental (non-FDA-approved) drug or device, include information that the FDA may inspect research-related records and that the subject's identity would then be known to the FDA. An identical disclosure should be included if the sponsoring drug company requests access to patient/subjects' research related records.
21. If research includes investigational drugs and women of childbearing potential, provide this statement regarding risk to fetus.
22. In studies of greater than minimal risk (see Definition in Human Subject Protection Application), include this statement verbatim.
23. Include statement #23 of the consent form **verbatim**.
- 24a. If the research project is classified as "medical experimentation", California law requires inclusion of statement #24 of the consent form **verbatim** and compliance with these terms
- 24b. All other "non-medical experimentation" informed consent forms must include statement #24b (see sample consent form).
25. Provide a signature line with provision for dating the subject's signature; witness is not required, but is desirable, and should be someone other than the investigator. This implies witnessing of the informed consent process.
26. If the subject is a legal minor, provision should be made for him/her to sign in addition to parents or guardians where appropriate.

14. SAMPLE CONSENT FORM

Date of Preparation _____

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Loyola Marymount University

(Title in Lay Language)

1) I hereby authorize (name & degree) to include me (my child/ward) in the following research study:

_____.

2) I have been asked to participate on a research project which is designed to _____ and which will last for approximately _____.

3) It has been explained to me that the reason for my inclusion in this project is because _____ (e.g., I am a student, female, etc.)

4) I understand that if I am a subject, I will _____.

The investigator(s) will _____.

These procedures have been explained to me by (Name and Qualifications) .

5) I understand that I will be videotaped, audiotaped and/or photographed in the process of these research procedures. It has been explained to me that these tapes will be used for teaching and/or research purposes only and that my identity will not be disclosed. I have been assured that the tapes will be destroyed after their use in this research project is completed. I understand that I have the right to review the tapes made as part of the study to determine whether they should be edited or erased in whole or in part.

...or...

I agree that the tapes shall be retained for research and/or teaching purposes for an indefinite time.

6) I understand that the study described above may involve the following risks and/or discomforts: _____.

7) I also understand that the possible benefits of the study are _____.

OR: I understand that I will receive no direct benefit from my participation in this study; however, the possible benefits to humanity include

- 8) I also understand that the following alternative procedures (and/or drugs) are available. The reason these are not being used is:

_____.

- 9) If any of the cells obtained from my blood are used to establish a cell line which may be shared in the future with other researchers and which may be of commercial value, I (do____, do not____) (Circle one and initial) voluntarily grant to the Loyola Marymount University any and all rights I, or my heirs, may have in any cell line or any other potential product which might be developed from the blood, bone marrow, and/or other materials obtained from me. A cell line is one that will grow indefinitely in the laboratory. Cell lines may be useful because of the characteristics of the cell and/or the products that may produce.

- 10) I understand that _____ who can be reached at _____ will answer any questions I may have at any time concerning details of the procedures performed as part of this study.

- 11) If the study design or the use of the information is to be changed, I will be so informed and my consent reobtained.

- 12) I understand that I have the right to refuse to participate in, or to withdraw from this research at any time without prejudice to (e.g., my future medical care at LMU.)

- 13) I understand that circumstances may arise which might cause the investigator to terminate my participation before the completion of the study.

- 14) I understand that no information that identifies me will be released without my separate consent except as specifically required by law.

- 15) I understand that I have the right to refuse to answer any question that I may not wish to answer.

- 16) Some of the information with which I will be provided may be ambiguous, or inaccurate. However, I will be informed of any inaccuracies following my participation in this study.

- 17) I understand that I will receive \$_____ for my participation in this study; I further understand that if I withdraw before the study is completed I will receive only \$_____. I understand that in the event my participation is terminated through no fault of mine, I will be compensated in the amount of \$ _____.

- 18) I have been informed that my insurance carrier and I are financially responsible for _____.

- 19) I understand that the Food and Drug Administration and (identify sponsoring drug company) may inspect the records relating to my participation in this study, therefore, my identity will be known to those agencies /companies.
- 20) If I am a woman of childbearing potential, due to the possible risks to the fetus, I will not participate in this research study unless, with the investigator's knowledge and approval, I am using a medically acceptable form of birth control (contraception).
- 21) I understand that in the event of research related injury, compensation and medical treatment are not provided by Loyola Marymount University.
- 22) I understand that if I have any further questions, comments, or concerns about the study or the informed consent process, I may contact Birute Anne Vileisis, Ph.D., Chair, LMU Institutional Review Board, 1 LMU Drive, Suite 3000, Loyola Marymount University, Los Angeles CA 90045-2659 (310) 338-4599, bvileisis@lmu.edu.
- 23a) In signing this consent form, I acknowledge receipt of a copy of the form, and a copy of the "Subject's Bill of Rights".
- 23b) In signing this consent form, I acknowledge receipt of a copy of this form.

24) Subject's Signature _____ Date

Date _____

Witness _____

...or...

25) Subject is a minor (age____), or is unable to sign because

Mother/Father/Guardian

Date

15. Child's Assent

In March of 1983 the Department of Health and Human Services issued the most recent human subject regulation, i.e., "Additional Protection for Children Involved as Subjects in Research" (45 cfr 46-Subpart D).

These regulations governing children in research situations decree that investigators need to take into consideration age, maturity, and psychological state of the participating children and include them in the consent process; having the older and more mature sign the informed consent form, and soliciting the assent of younger children. The regulation defines "assent" as the child's affirmative agreement to participate. "Mere failure to object should not, absent affirmative agreement, be construed as assent."

The following items should be addressed in an assent procedure utilizing language appropriate to the child's age and/or developmental level:

- Why the child is asked to participate;
- What is going to take place in the child's point of view;
- The risk to the child;
- The benefit to the child; and
- Identification of the researcher by name and telephone number in case questions should arise.

In non-therapeutic research, a statement that the child has a choice to participate or withdraw at any time without negative consequences:

- A statement that the child may retain a copy of the assent form; and date and signature lines for the researcher and, if appropriate, for the child.