

IUE Institutional Review Board (IRB)

Instructions and Forms
for Approval of Research Involving Human Subjects

BY FEDERAL LAW AND UNIVERSITY POLICY, ALL RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS MUST RECEIVE THE APPROVAL OF THE CAMPUS INSTITUTIONAL REVIEW BOARD. THIS POLICY APPLIES REGARDLESS OF THE FUNDING SOURCE OF THE RESEARCH.

To IUE Researchers:

The attached instructions and forms are designed to cover a wide variety of research situations, many of them governed by very precise federal regulations. While the packet may appear daunting at first, in practice most researchers will need to deal with only a small part of it.

Before proceeding with this packet, if you have not already done so, be sure to obtain and read a copy of the following documents:

Guidelines and Policies for Investigators – available from Academic Affairs

Indiana University's Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects – available on the WWW at <http://www.iupui.edu/%7Eeresgrad/spon/assurance.htm>

45 CFR 46 of the Code of Federal Regulations, Protection of Human Subjects – available at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

The Belmont Report – a national commission report on the ethical guidelines for research with human subjects – available at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

To make the task as simple as possible, begin with the three decision trees that follow this page; they should guide you through the process and indicate which of the rest of the package, if any, you need to complete. This part is as easy as 1-2-3:

1. Decide **which IRB process**, if any, is required. If one of the three IRB review processes is required, then
2. Decide **which documents** must be filed, and
3. Decide whether **any special protections for vulnerable populations** are required.

Based on these decisions, complete and file any documentation required, following the instructions on the various forms. You will receive written notification within one week after the IRB action on your proposal; research with human subjects may not begin until IRB approval is secured. You will be asked to file a brief status report annually while the research is continuing, to secure approval for **any** changes in the research protocol, and to file a final report upon the completion of the research project.

If you have any questions at any point, you are encouraged to contact the Office of Academic Affairs or any IRB member for assistance. We want to make it possible for each IUE investigator to meet all legal requirements and ethical concerns as fully as possible and with as little difficulty as possible. We welcome your suggestions in this regard.

DECISION 2
WHAT DOCUMENTATION MUST BE FILED?

If the required IRB process is:

Then file the following documents as indicated:	Exempt	Expedited	Full Review
Exempt review checklist (See pp. 9-10)	Required		
Expedited review checklist (See pp. 11-14)		Required	
Documentation of review and approval form (See p. 15)		Required	Required
Summary Safeguard Statement and Protocol (See pp. 16-17)	Required	Required	Required
Informed Consent Statement (See pp. 18-22)	Include as applicable	Required	Required
Instruments ¹	Required	Required	Require
Advertisements ²	Include as applicable	Include as applicable	Include as applicable
Cooperating Departments or Institutions ³	Include as applicable	Include as applicable	Include as applicable

For instructions on when, where, and how many copies to file, **go to the next page.**

¹Include copies of any questionnaires or other survey instruments to be used.

²If the proposed research is regulated under FDA requirements, i.e., investigational drugs or devices will be used, the written advertisements used to recruit research subjects must be included along with the mode of communication at the time of protocol submission.

³If it is anticipated that another department may be involved in the research, include a co-investigator from each cooperating department or a letter of cooperation indicating the department's willingness to be involved in the study; if the study will be conducted with another institution, include a letter of cooperation from that institution.

When, where and how many copies to file:

IRB Process:	Number of copies:	Submit to:	Lead time recommended:
Exempt	Two	IRB Chair Academic Affairs 262 Whitewater Hall ¹	One Week Prior to IRB Meeting ²
Expedited	Four	IRB Chair Academic Affairs 262 Whitewater Hall	One Week Prior to IRB Meeting ²
Full Review	Seven	IRB Chair Academic Affairs 262 Whitewater Hall	Two Weeks Prior to IRB Meeting (See Semester Calendar ³)

BEFORE PROCEEDING TO COMPLETE AND SUBMIT THE REQUIRED DOCUMENTATION, GO TO DECISION 3, ON THE FOLLOWING PAGE.

¹or directly to Chairperson when known.

²The lead times indicated for exempt and expedited reviews assume a favorable decision. No proposal may be denied approval by an exempt or expedited process; it must be either approved or referred to the IRB for full review. In the latter case, more time will be required. Early submissions will increase the opportunity for discussion and a timely resolution of any issues that may arise.

³ The IRB meeting calendar will be published within the first week of each semester.

IUE Institutional Review Board (IRB)
EXEMPT RESEARCH CHECKLIST

This form is to be completed and submitted to the IRB only when the investigator is contemplating the initiation of a research project that, in the investigator's judgment, is exempt from normal IRB review. The IRB will then determine whether or not the activity is covered by these regulations.

Research activities are exempt from regulations for the protection of human research subjects when the ONLY involvement of human subjects fall within one or more of the categories below. These exemptions do not apply to research involving prisoners, fetuses, pregnant women, human In vitro fertilization, or when there is additional involvement of human subjects beyond the categories listed below, when deception of subjects may be an element of the research, when the activity might expose the subject to discomfort or harassment beyond levels encountered in daily life. The exemption of category 2 of exempt research does not apply when individuals under the age of 18 are subjects of the activity, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. Check the appropriate categories that apply to your research project:

- _____ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- _____ 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the following two conditions exist: (i) information taken from these sources is recorded in such a manner that the subjects can be identified, directly or through identifiers linked to the subject; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- _____ 3. All research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey, or interview procedures or observation of public behavior that is not exempt under category 2 above, (i) if the subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- _____ 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject.
- _____ 5. Research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- _____ 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

IUE Institutional Review Board (IRB)
EXPEDITED REVIEW CHECKLIST¹

This form is to be completed and submitted to the IRB when the investigator is contemplating the initiation of a research project that, in the investigator's judgment, qualifies for expedited review by the IRB. If "yes" is the response to items 10 and/or 11, the study does not qualify for expedited review (full review will be required). Items 1-9 are the categories that may qualify for expedited review.

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories in this list apply regardless of the age of subjects, except as noted. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

- | Yes | No | |
|-------|-------|--|
| _____ | _____ | 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
| _____ | _____ | 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children ² , considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50ml |

or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- _____ 3. Prospective collection of biological specimens for research purposes by noninvasive means.
- _____ 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared devices for new indications.)
- _____ 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). this listing refers only to research that is not exempt.
- _____ 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
- _____ 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural belief or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). this listing refers only to research that is not exempt.
- _____ 8. Continuing review of research previously approved by the convened IRB as follows:
 - (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for the long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) where the remaining research activities are limited to data analysis.

- _____ 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- _____ 10. Does this project include any procedures not listed above?
- _____ 11. Does this project include any procedures presenting more than minimal risk to the subject?

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experience reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45CRF 46.110.

² Children are defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

IRB Rev. 9/99

IUE Institutional Review Board (IRB)
DOCUMENTATION OF REVIEW AND APPROVAL

Project Title: _____

Anticipated Duration of the Study: _____ from _____ to _____

If applicable:
Sponsoring Agency: _____

Grant No. _____ Period: _____ from _____ to _____

Principal Investigator (Must have faculty/staff status):

Typed or Printed Name Signature Date

Campus Address: _____
Department Telephone Number

Check Type of Review: _____ Expedited
_____ Full

Check if the research subjects are any of the following:

_____ Minors _____ Fetuses _____ Economically or
_____ Pregnant Women _____ Abortuses _____ Educationally
_____ Mentally Disabled _____ Prisoners _____ Disadvantaged

OTHER REVIEWS: If the research involves infectious wastes, hazardous chemicals, or the use of radiation and/or radioactivity, contact the Director of Physical Plant (973-8218) for the name of the University official or committee for the name of the University official or committee currently responsible for these specific environmental health and safety matters.

The principal investigator must assure the Board that all procedures performed under the project will be conducted in accordance with those federal regulations and University policies which govern research involving human subjects. **Any substantial change in the project (e.g., change in principal investigator, research methodology, subject recruitment procedures, etc.) will be submitted to the Board in the form of an amendment for its approval prior to its implementation.**

Date Principal Investigator (signature)

This proposal for the use of human subjects has been reviewed and ___ approved ___ denied by the Indiana University East Institutional Review Board.

Committee Chair Date

IUE Institutional Review Board (IRB)
SUMMARY SAFEGUARD STATEMENT AND PROTOCOL

The IRB needs sufficient information about your proposed research in order to make judgments about the protection of human subjects of research. To provide that information, please answer **all** questions, maintaining the order and numbering below. Submit your responses typed on separate paper with your request for IRB review.

1. **Give the project title.** Add an alternate lay title if the nature of the research or the subject population will make it impractical to use the formal title of the Informed Consent form.
2. **Give a brief summary description of the proposed research:**
 - a. **Who** will conduct the research?
 - b. **What** is to be done?
 - c. **When** and **where** will the research be conducted?
 - d. What is the **purpose and rationale for the research?**
3. **Describe the subject population:**
 - a. What are the **specific eligibility requirements** for subjects?
 - b. **What criteria would exclude otherwise acceptable subjects?**
 - c. **How will subjects be recruited?**
 - d. Will the research deal with any of the following **subject populations specially protected** under federal regulations: minors, fetuses, abortuses, pregnant women, mentally disabled, prisoners, economically or educationally disadvantaged? If yes, state which special population(s) and explain the necessity for doing so.
4. **List all procedures to be used on human subjects.** Asterisk any procedures that depart from commonly accepted practice in the field, and explain why the usual method(s), if any, are not to be used.
5. **Describe how risks to subjects are reasonable in relation to anticipated benefits, including the following points:**
 - a. **the risks** (e.g., physical, psychological, social, legal) **connected with the proposed procedures:**
 - b. **the procedures for protecting against or minimizing risks and their likely effectiveness:**
 - c. **the benefits, if any, to be gained by the subject:**

In the event of monetary gain, include all payment arrangements (amount of payment and the proposed method of disbursement), including reimbursement of expenses. Explain if there will be any partial payment if the subject withdraws prior to completion of the study.
 - d. **the information that may accrue to science or society in general as a result of this research.**

SUMMARY SAFEGUARD STATEMENT (continued)

6. **List the Principal Investigator and any co-investigators.** If you anticipate that another department may be involved in this research, include a co-investigator from that department or a letter of cooperation indicating the department's willingness to be involved in this study. (If there are multiple investigators, please indicate only one person as the principal investigator; others should be designated as co-investigators.)
7. If the study involves the use of new drugs or devices, the following information is required by the Food and Drug Administration:
- a. Name of drug sponsor: _____
IND Number: _____ Phase I, II, or III Study: _____
- b. Name of device manufacturer: _____
IDE Number: _____
Significant risk _____ Nonsignificant risk _____
Investigator's assessment of the device risk: _____

IUE Institutional Review Board (IRB)

INFORMED CONSENT STATEMENT

The IRB Informed Consent Statement Form has two purposes: (1) to enable potential research subjects to make an informed choice as to their participating in a study, and (2) to document their decision to participate.

In order to make an informed choice, potential subjects must understand their part in the study and the risks it poses to them. Therefore, the first part of the form consists of explaining the study from the subject's point of view: how it will involve him or her, what sort of risks he or she undertakes in participating, what to do if something untoward happens. Obviously, the words and language used to describe these factors must be understandable to the potential subject.

The second part of the form consists of proper documentation that the subject, having heard or read the pertinent material, gives his or her consent to participate in the study.

Next is a set of tips on informed consent from the Office for Protection from Research Risks. This is followed by a checklist of the required components of the consent form for use by the investigator in constructing the consent form.

Office for Protection from Research Risks

TIPS ON INFORMED CONSENT

The process of obtaining informed consent must comply with the requirements of **45 CFR 46.116**. The documentation of informed consent must comply with **45 CFR 46.117**. The following comments may help in the development of an approach and proposed language by investigators for obtaining consent and its approval by IRBs:

- ?? Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

- ?? Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.

- ?? **Describe the overall experience that will be encountered.** Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.
- ?? **Describe the benefits that subjects may reasonably expect to encounter.** There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.
- ?? **Describe any alternatives to participating in the research project.** For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- ?? **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence.** For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality that protects the investigator from involuntary release (e.g. subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.
- ?? **If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see 45 CFR 46.102[g]), an explanation must be given of whatever voluntary compensation and treatment will be provided.** Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation.
- ?? **The regulations prohibit waiving or appearing to waive any legal rights of subjects.** Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.
- ?? **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation.** Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These

questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

- ?? **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations (45 CFR 46.116[a][8]).** It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.
- ?? Don't forget to ensure provision for appropriate **additional requirements** which concern consent. Some of these requirements can be found in sections [46.116\(b\)](#), [46.205\(a\)\(2\)](#), [46.207\(b\)](#), [46.208\(b\)](#), [46.209\(d\)](#), [46.305\(a\)\(5-6\)](#), [46.408\(c\)](#), and [46.409\(b\)](#). The IRB may impose additional requirements that are not specifically listed in the regulations to ensure that adequate information is presented in accordance with institutional policy and local law.

Revised 3/16/93

§46.116 - Informed Consent Checklist - Basic and Additional Elements

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to the subject or to others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
<input type="checkbox"/> Research Qs	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
<input type="checkbox"/> Rights Qs	
<input type="checkbox"/> Injury Qs	
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
Additional elements, as appropriate (required unless IRB concurs otherwise):	
	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
	The approximate number of subjects involved in the study

§46.117 Documentation of Informed Consent Checklist

<p>a. Except as provided in paragraph "c" of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.</p>	
<p>WRITTEN</p>	<p>The consent form may be either of the following:</p> <ol style="list-style-type: none"> 1. A written consent document that embodies the elements of informed consent required by <u>§46.116</u>. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
<p>DONE ORALLY</p>	<ol style="list-style-type: none"> 2. A short form written consent document, stating that the elements of informed consent required by <u>§46.116</u> have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
<p>WAIVER of req't for signed form</p>	<p>c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:</p> <ol style="list-style-type: none"> 1. That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or 2. That the research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context. <p>In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.</p>