
SUBJECT: Principal Investigators Manual for Research Involving Human Subjects

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** Note: Please read this manual carefully. It contains important information that will help you complete the "Application to Use Human Subjects in Research" form. Failure to follow instructions may result in a delay in the approval process.

THE PURPOSE OF THIS MANUAL

This manual is intended as a guide for faculty, students, staff, and any other members of LSU Eunice who plan to carry out research, whether funded or unfunded, involving the participation of human subjects. It provides basic information about what materials are needed and the process to use in requesting approval to use human subjects in research.

All research that is conducted by an individual in connection with his or her institutional responsibilities and/or which involves the use of any of the University's property or facilities must conform to a standard of ethics reflected in specific regulations of the United States Department of Health and Human Services (DHHS) in order to assure that the rights and welfare of human subjects are protected.

INTRODUCTION

Research with human subjects which is conducted by any member of the LSU Eunice community or anyone using LSU Eunice facilities, must be reviewed and approved by an LSU Eunice Institutional Review Board (referred to hereafter as the IRB). The IRB's interest is in protecting the safety, welfare, privacy and rights of human research subjects. It is not the IRB's objective to pass judgment on other aspects of the research (e.g., scientific merit). With the above goal in mind, the application for review of research involving human subjects must contain specific information. This information allows the IRB to evaluate the:

1. risks to subject(s);
2. specific nature of subjects' participation including:
    a) recruitment of subjects,
    b) voluntary nature of subject participation,
    c) informed consent,
    d) remuneration (if any) to subject,
    e) specific procedures to be followed.

In order to submit research for review, investigators must complete the APPLICATION FOR APPROVAL TO USE HUMAN RESEARCH SUBJECTS IN RESEARCH, which may be obtained from the office of the Vice Chancellor for Academic Affairs.

The most important concerns of the IRB are to assure subjects' safety, preserve subjects' anonymity and confidentiality, and assure that participation is voluntary. Thus, the application should contain information related to these areas. For example, a question of coercion may arise when an instructor solicits students from his/her own classroom for participation in a research project in which the instructor is involved. Another concern is the desire for subjects to be fully informed of the procedures to be

employed in the study and of possible adverse effects. Also, the procedures should not coerce subjects to continue in a study if they desire to stop participation.

In order to facilitate approval of the application for use of human subjects in research, it is necessary for all relevant information to be included in the application. It is of equal importance that the document present a clear and concise explanation of the proposed research project. Delays in approval by the IRB can be caused by: (a) insufficient information; (b) relevant information being omitted from the application (or placed in appendices rather than in the text of the application); (c) presenting information in a manner that is too technical and cannot be understood by IRB members whose backgrounds and areas of expertise vary greatly and (d) the consent document contains grammatical and/or spelling errors or its language is inappropriate to the subject population being targeted.

IRB COMPOSITION

1. The Institutional Review Board will have the following composition: a representative from each of the academic divisions, a representative from the professional staff, and a representative from the LSU Eunice Board of Advisors.
2. The academic representatives will be elected by their respective academic units at their first meeting of the academic year. The representative from the professional staff will be selected in a manner to be determined by the Staff Senate. The representative from the LSU Eunice Board of Advisors will be selected by the Academic Council.
3. The members will serve for an academic year.
4. The Vice Chancellor for Academic Affairs will call the first meeting, at which time a chair will be elected by the members of the IRB.
5. Following the initial organizational meeting, the IRB will meet once a month to review applications. However, if no applications have been submitted by the customary meeting date, the IRB will not meet until the following month.

DEFINITIONS

1. Human Subject - "Human Subject**"** is a living person about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the person, or (b) identifiable private information.
2. Intervention - "Intervention" includes both physical procedures by which data are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
3. Interaction - includes communication or interpersonal contact between investigator and subject.
4. Minimal Risk - "Minimal Risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

5. Private Information - "Private Information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for the process of obtaining the information to constitute research involving human subjects.
6. Research - "Research" means systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to the generalizable knowledge. Activities which meet this definition constitute research for purposes of this assurance, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
7. Established and Accepted Methods - Some methods become established through the rigorous standardization procedures prescribed by law, as in the case of drugs, devices, or biologicals, by operation of law, or, as in the case of many educational tests, under the aegis of professional societies or non-profit agencies. Determination as to when a method passes from the experimental stage and becomes "established and accepted" is a matter of judgement.
8. Legally Authorized Representative - "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the procedure(s) involved in the research.
9. IRB - "IRB" means an Institutional Review Board established in accord with the basic DHHS policy for the protection of human research subjects (45 CFR Part 46) and for the purposes expressed in that policy.
10. IRB approval - "IRB approval" means the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other applicable institutional, statutory, and regulatory requirements.

INSTRUCTIONS FOR COMPLETING THE "APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH"

Please Note: The application should stand on its own, without reference to any attached grant proposals or articles published, in press, or under review. (Just cutting and pasting paragraphs from a grant proposal causes confusion during the review process.) In addition, information placed in appendices may be overlooked. The application should provide all information necessary for IRB members unfamiliar with the experimenter's field of research to be able to evaluate the risks to subjects, how subjects will be recruited, the potential benefits, and how informed consent shall be obtained.

Page 1, Question 1: If you are seeking IRB approval as part of a grant application process, the title of the project should be the same on both the "Application for Approval" and within the grant proposal.

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Page 1, Questions 2 and 3: PI's & Co PI's may list contact information other than their regular campus address in this space if they prefer to be contacted elsewhere. Co-PI's who are neither employees nor students of LSU Eunice should list full information about their affiliation here.

Page 1, Question 4: Check "Other" if you are not affiliated with LSU Eunice but are seeking to conduct research involving the LSU Eunice community or the use of LSU Eunice facilities.

Page 1, Question 5: All student research must be approved by a faculty advisor before it is submitted to the IRB for review.

Page 1, Question 6: Choosing the appropriate type of review: The initial determination about the type of review appropriate to the project will be made by the Principal Investigator. However, if in the opinion of the IRB, another type of review is more appropriate, the project will be reviewed under that review procedure and the PI notified. On occasion, the IRB may request additional documentation in order to determine if the use of a particular type of review is justified.

EXEMPT REVIEW PROCEDURES

Federal regulations "exempt" some types of research from regular review procedures by the IRB, though use of this term can be confusing. "Exempt" research is in fact reviewed, though ordinarily not as much documentation is required (in these cases, only the first three pages of the APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH need be submitted). If found exempt, the project need not follow continuing review procedures unless significant changes are made to the research protocol. Federal regulations permit the Principal Investigator to make the initial determination as to whether the project is exempt. The categories of research detailed below are exempt from review.

Categories of Research eligible for Exempt Review Procedures:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education 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 if: i) information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects, and ii) any disclosure of subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation (including observation by participants) of public behavior, that is not exempt under (2) of this section if: (i) the subjects are elected or appointed public officials or candidates for public office; or (ii) 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 subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are: (i) designed to examine current 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 (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 the level for use found to be safe, or agricultural chemical or environmental contaminant at the level found to be safe, by the Food and Drug Administration or approved by the EPA or Environment Protection Agency or the Food Safety and Inspection Service of the USDA.

Non-HHS-supported research that presents no more than minimal risk to a subject (i.e., not exceeding risk ordinarily encountered in daily life) may be approved by expedited review if it falls into one of the following categories:

1. Collection of hair and nail clippings in a non-disfiguring manner, deciduous teeth, and permanent teeth if patient care indicated a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects eighteen years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and

electroretinography. This does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week from subjects eighteen years of age or older and who are in good health and not pregnant.

5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Research that involves more than minimal risk, or is not covered by the categories listed previously, requires full review. Reports of research approved under expedited or exempt procedures are made at each regular IRB meeting.

HAVE QUESTIONS ABOUT WHICH TYPE OF REVIEW TO SELECT?

A complete application is necessary for both full and expedited categories of research proposals. According to Federal Regulations, if the IRB member(s) assigned for expedited review have questions about the appropriateness of expedited review or concerns about the nature of human subjects participation, the proposal is reviewed by the full IRB at its next meeting.

The IRB can provide advice and assistance to help investigators determine if projects are exempt.

Page 1, Question 7: All research that involves fetuses, pregnant women, prisoners, or groups who may have diminished capacity to provide consent or who may be high risk, must be provided full review. Most research involving minors falls into this category as well.

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RESEARCH INVOLVING CHILDREN AS SUBJECTS

Children are considered a vulnerable and therefore "protected" population in the context of serving as research subjects. In Louisiana, children are defined as those persons who are under 18 years old and have not obtained the legal age for consent to treatment or procedures involved in the research.

In addition to those materials normally required for review by the IRB on the Protection of Human Subjects, a parental or guardian consent form, including all traditional elements of informed consent, is required. A child assent form should be used for child subjects 12 years of age or older. Language should be understandable and include a brief description of the task(s) involved and a statement on the right to withdraw at any time without penalty. For subjects under 12 years of age, an assent procedure should be employed. Assent is defined as an affirmative agreement (as opposed to tacit consent) to participate in research.

If child subjects are being obtained from another institution(s), written permission from an official from the institution(s) authorized to do so, must accompany the protocol.

Federal policy dictates that the use of prisoners as human research subjects is strictly prohibited without the prior approval of the Human Subjects IRB. This restriction also applies to the compassionate use of investigational agents or devices on prisoners.

If prisoners are to be potential subjects of a project, the researcher must indicate this in the application. If a Principal Investigator plans to have prisoners as subjects in his or her research project, please contact the IRB Office before finalizing the protocol. Additional time may be necessary to process proposals involving prisoners as subjects since the IRB will need to refer the proposed project to an individual or individuals who will have been designated as prisoner advocate(s). These precautions are mandated by the Federal regulations governing research involving human subjects. Copies of these regulations are available from the IRB. Written permission will need to be obtained as well from the cooperating institution from which subjects will be recruited.

Page 2, Question 8: The investigator is justified in withholding information from or giving incomplete or erroneous information to research subjects only when it can be demonstrated that the research cannot be conducted in any other way and that subjects will not be placed at risk. Research involving deception must be provided full review. At the earliest possible moment consonant with the validity of the research, the subject should be informed of the actual purpose of the research and procedures must be developed to relieve any distress encountered. All research involving deception must have attached to it a full description of the debriefing procedure to be used to the application.

Page 2, Question 9: Subjects at Risk: "Subjects at risk" means any individual who may be exposed to the possibility of injury, e.g. physical, psychological, or social injury, as a consequence of participation as a

subject in any research or related activity which departs from the application of those established and accepted methods necessary to meet his needs or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. When reviewing protocols with more than minimal risk to subjects, the IRB may delay approval of a protocol and make recommendations to the investigator for alterations in the wording of informed consent documents or for changes in the protocol to further minimize potential risks to subjects. Research may not begin until IRB approval has been granted.

Page 2, Question 10: The IRB grants approval for one year from the date of initial approval only, regardless of when research actually begins. If, for example, funding was sought but not received from one source, but later received from another source, the project must be reapproved if more than a year has elapsed.

Page 2, Questions 11 and 12: Answering these questions aids the IRB to ensure all required documentation is in place.

Page 2, Question 13: Certain research projects will involve hospitals, schools, organizations, etc., that are not affiliated with LSU Eunice. In such cases, the Principal Investigator is required to obtain a copy of the organization's agreement to participate and/or, if applicable, that institution's IRB approval before the recruitment of subjects may begin. For research that requires IRB approval by more than one institution, protocols must be identical.

Deadlines

The IRB's practice is to circulate applications requiring full or expedited review to IRB members prior to the meeting. Any questions, comments or concerns raised by members are discussed at the next meeting and transmitted in writing after the meeting to the Principal Investigator for a written response.

It is the Principal Investigator's responsibility to see that the application is complete (i.e., all questions are answered), that required materials are attached (e.g., a copy of the informed consent form to be used), and that the application is submitted prior to the next IRB meeting. **LSU Eunice requires submission of applications at least 10 days before the IRB meeting. Failure to adhere to these requirements may lead to a delay in review and/or approval.**

Special Deadline Considerations

Investigators should be aware that for non-competing continuation applications, the National Institutes of Health require IRB approval coincident with the grant/contract/funding application. This means that the Human Subjects review must take place prior to submission of the grant application.

It is suggested that Investigators submit requests for Human Subjects review prior to or as soon as possible after submitting the proposal to the IRB Office to prevent a delay in the awarding of funds.

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EXEMPT REVIEW (page 3)

To request an exemption, simply select one of the six categories on page three of the "Application" and append a written justification for your request to it. This justification should include information on the subject population, the means of subject selection, how anonymity will be assured and what informed consent procedures, if any, will be followed. If your research involves surveys which have already been prepared, append them as well. Failure to provide the IRB with a sufficient justification of your request for an exemption will result in delays in approval. If for any reason the IRB finds it cannot grant your project an exemption, the project will undergo either expedited or full committee review as the Chair sees fit. In such cases, you may expect to be asked to provide additional information.

EXPEDITED OR FULL IRB REVIEW (page 4)

Page 4, Question 1: The description of your research should be in language that can be understood by non-experts in your field and should be in detail sufficient for the IRB to make a judgement about the adequacy of the human subjects protections proposed. Such protections are the only concern of the IRB; judgement about a particular project's validity or feasibility lay outside its jurisdiction.

Page 4, Question 2: Various sub-topics follow

SELECTION AND RECRUITMENT OF SUBJECTS FOR PARTICIPATION IN RESEARCH

When selecting subjects for research, it is important to consider carefully the category of subjects being chosen. Federal guidelines require a scientific justification if women and/or minorities are to be excluded from a subject population. In addition, vulnerable populations, e.g., prisoners, pregnant women, institutionalized individuals, or children, are to be studied only under certain conditions, and only if the study could not be undertaken without them.

When recruiting subjects for research, it is important to follow procedures that will ensure that subject participation is truly voluntary and that no procedures that could be construed as even minimally coercive have been employed. The preferred method of recruitment is to disseminate information about the research study to potential subjects and to instruct them to contact the investigator if they are interested in participating. In the interest of respecting individuals' rights to privacy and confidentiality, recruitment procedures should involve having interested subjects identify themselves to the investigator rather than the investigator obtaining names and addresses from a third party and soliciting participation directly from individuals. Some acceptable and non-intrusive means of recruiting subjects are listed below.

ACCEPTABLE MEANS FOR THE SELECTION AND RECRUITMENT OF SUBJECTS FOR PARTICIPATION IN RESEARCH:

1. Placing an advertisement in a periodical or Web site requesting that interested persons who meet relevant criteria contact the investigator.

2. Posting a sign or placing flyers in a public area or, with permission from the appropriate authority, in a private area (such as a university, store, library, health club, etc.) requesting that interested persons who meet relevant criteria contact the investigator.

3. Obtaining names from public records, such as telephone directories.

4. Obtaining names from organization membership or client records to which the investigator has legal access and for which s/he has obtained permission from the appropriate authority.

Researchers should avoid using their own patients or students as subjects due to the nature of the existing relationship and the unavoidable potential coercion. When recruiting subjects from hospitals, private medical or psychotherapy practices, schools, religious groups or businesses, steps should be taken to ensure that potential subjects do not feel obligated to participate because they wish to please an authority figure who they believe wants or expects them to participate. Every effort should be made to use recruitment procedures that do not involve the referring doctor, teacher, therapist, cleric, etc., knowing which individuals eventually participated in the study. To fulfill this objective, subjects should be recruited in these circumstances with minimum direct involvement of the referral source. Whenever possible, the investigator should request that the referral person simply inform clients of the study and instruct them to contact the investigator if they would like to participate. Names and addresses of potential subjects should never be directly requested from referral sources unless permission has been given by these individuals to release their names.

In a hospital-based study, particularly when there may be medical or emotional contraindications to participation, it is necessary to obtain approval from patients' physicians prior to their participation. Thus, in addition to selecting patients who meet specific criteria to be eligible to participate, the referring physician or other health care professional should also select patients on the basis of who is deemed to be both competent to give informed consent and capable of carrying out the required tasks without jeopardizing his/her health and safety.

In certain cases, a subject's right to privacy may be superseded by a desire to minimize coercion. In a corporate setting, for example, a researcher who personally has access to a personnel roster may be justified in approaching subjects directly if it means that the employer is thereby disassociated from the recruitment process and will not have access even to a list of potential subjects. A discussion of the merits of direct recruitment should be included in the Application for Approval to Use Human Subjects in Research. Steps for protecting the confidentiality of the data to be obtained and the anonymity of the subjects are of paramount concern when employees are being asked to participate at their place of business. In summary, names of potential subjects are not to be obtained from hospitals or private practices unless the referral agent has obtained permission from each individual to release the name. Whenever possible, potential subjects should be informed of research indirectly and instructed to contact the investigator if they are interested in participating. To reach specific populations independent of a third

party referral source, information can be disseminated in written form in periodicals, by posting a sign in a convenient place or arranging to have flyers distributed to eligible individuals. A description of a research study may also be presented verbally to groups or individuals, preferably by someone whose position or relationship to potential subjects will not create pressure, or perceived pressure, for individuals to comply.

ACCESS TO EDUCATIONAL AND/OR SCHOOL RECORDS.

Investigators who require access to educational and/or demographic records must negotiate with those institutions for access to that information. The IRB will not approve any application unless access to that information already has been granted by the appropriate institution. If the outside institution requires IRB approval, the IRB may approve the application contingent upon the outside institution's approval. Agreement to provide information by outside institutions does not obligate the IRB to approve the project.

The IRB expects the same standards of confidentiality and anonymity to be exercised with information obtained from other institutions as is required for information obtained from LSU Eunice.

USE OF STUDENTS ENROLLED IN A COURSE.

The IRB is required to ensure that a subject's participation in research is voluntary. Thus, practices such as: (i) recruiting subjects from a course in which the investigator is also instructor; and/or (ii) offering extra credit and/or inducements which affect the course grade unless comparable opportunities are offered to non-participants, are usually not approved by the IRB.

Page 4, Question 3: Procedures to be followed. If for any reason your project involves experimental or non-standard means of collecting data where standard procedures exist, a justification for the use of the non-standard procedures should be included here.

Page 4, Question 4: Types and levels of risk.

In general, the higher the risk involved in the project, the more detailed the explanation, precautions, and informed consent must be. The nature and type of informed consent is determined by the level of risk. Accordingly, the following broad guidelines for degrees of risk may be of assistance in making a necessary determination.

High Risk: Activities involving medical or behavioral science projects that may induce a potentially harmful altered physical or mental state or condition are forms of personal invasion and, as such, are considered to be in a "high risk" category. (Examples include biopsy procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exercise; hypnotism; and subjection to deceit, public embarrassment and humiliation.) In these cases there must be especially careful documentation to show that the benefits outweigh the risks.

Intermediate Risk: Activities involving a wide range of medical, social, and behavioral projects in which there is no immediate physical risk to the subject are considered to be in an "intermediate risk" category. (Examples include personality inventories; interviews; questionnaires; the dissemination of any data or information concerning an identified individual; information gathering activities conducted in classrooms or elsewhere; individual or group therapy sessions; or the use of photographs, taped records, and stored data.) Since some of these types of procedures may involve varying degrees of dignity through the imposition of demeaning or dehumanizing conditions, prior written informed consent is also required. However, since this type of activity does not involve physical invasion but is an activity where voluntary consent on the part of the subject is desirable, a more simplified consent is acceptable.

Low Risk: Certain activities are classified as "low risk" and may not require a written informed consent. (An example is the use of completely anonymous questionnaires.) If a written informed consent is deemed unnecessary or undesirable in a particular instance, there follows an additional responsibility to establish that:

1. the risk to the subject is minimal;
2. obtaining a consent would invalidate objectives of considerable immediate importance; and/or
3. any reasonable alternative means for attaining the objectives have been thoroughly explored and would be less advantageous to the subject.

Low risk involves situations in which there is no conceivable physical or mental discomfort, and the measurements made on subjects can be considered to be reasonably unobtrusive. In these situations written informed consent may be waived.

Page 4, Question 5: Confidentiality and anonymity: If a Federal Certificate of Confidentiality has been obtained or is being sought, this should be noted here and a copy provided if it is available.

Page 4, Question 6: Debriefing procedures/revelations of potentially troublesome situations. If individuals possessing any special skills or training are to be present during procedures, this should be noted here. Where possible, investigators should provide the IRB with a list of agencies, hospitals, professionals, etc., to whom they may refer subjects who reveal a need for such assistance.

Page 5, Question 7: Informed consent

The informed consent form is one of the most important portions of the APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH. The form must give a clear and concise explanation of the research to be conducted and the procedures to be employed. The form must be written in language appropriate for the targeted subject population (e.g., English and French versions should be written for a multi-cultural study).

An informed consent document, ideally should be one page in length. The form should be written in language that is age- and culture-appropriate. The statement should be written clearly enough for the

potential participant to understand what involvement in the study entails, so that she or he may make a reasonable, intelligent, and informed decision. The language should be kept simple, and the sentences short. The language of the form should be understandable at the eighth-grade reading level for studies using adult populations. The typeface should be large enough so that even subjects with impaired vision can read it.

It is possible that the research may produce psychological difficulties for a subject; therefore, it may be necessary to make arrangements for those difficulties to be dealt with by a professional. For example, in one study of people with chronic illness, the Investigator provided all subjects with a list of mutual-help organizations in the local area.

After review of the informed consent document, subjects should have a clear understanding of the procedures which will be followed with regard to their participation. Each subject should be able to make an informed decision concerning participation, free of explicit or perceived coercion. Potential risks and procedures to minimize such risks must be stated in detail in clear, precise language. A statement should be included in which the subject declares himself/herself fully informed and agrees to participate on a purely voluntary basis. Finally, the subject should be given a copy of the consent form, and/or any information sheets that he/she is required to read.

Copies of the completed informed consent forms should be retained by the Principal Investigator for a period of at least three years following termination of the project.

A copy of the sample consent form(s) to be used must be included with each APPLICATION FOR APPROVAL and must be approved by the IRB. At the time of approval, the consent form will be stamped with an expiration date, after which time it may not be used.

<u>Elements of the informed consent form</u>

The following elements must be included in the informed consent form:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental (e.g., in medical research, those procedures which deviate from standard, accepted practice). If the purpose of the research cannot be fully revealed to subjects, describe exactly what subjects will be told, the justification for any deception of subjects, and plans to debrief subjects after their participation in the research.
2. The name(s) and affiliation(s) of the Principal Investigator(s).
3. A description of any foreseeable risks or discomforts (both physical and mental) that could reasonably be anticipated.

4. A description of any benefits to the subject or to others which may reasonably be expected from the research. In most research, expected results are tenuous, at best. If no direct benefits due to participation are foreseen, it is appropriate to state this.
5. 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. If the participant has been promised financial compensation, but chooses to withdraw, state that a pro-rated portion of the fee will be paid up to the point of withdrawal.
6. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
7. A statement describing how anonymity and confidentiality will be maintained.
8. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained which should include how records will be kept confidential, (e.g., locked cabinet, erasing of tapes, etc.). If audio taping is to occur, indicate who will hear the tapes, where they will be stored, and how and when they will be disposed. If videotaping is to occur, indicate to whom the tapes are to be shown and where they will be stored.
9. The informed consent form must have a line for the subject's and researcher's signatures, and the date of consent. If the participation must be anonymous and the form is to be signed with an X, then the signature of a witness must also be obtained. The Investigator should retain a copy of the signed consent form and provide a copy to the subject.
10. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of research-related injury to the subject. The informed consent form should include a phrase such as the following: “If you have any questions concerning your rights as a participant in this study, you can call the Office of the Vice Chancellor of Academic Affairs.”

A note on language style

The language used in the consent from must be appropriate to the subject's level of education and understanding. Exculpatory language through which the subject is made to waive his/her legal rights or releases or appears to release the institution from liability for negligence may not be included. When applicable, a consent form should be translated into the subjects' first language.

The consent form, and any materials used to recruit subjects should be submitted to the IRB at the time application for human subjects approval is made. If these materials are written in a foreign language, both the forms to be used and their English translations are to be submitted.

Informed consent with minors as subjects

Children under age 18 are considered legally incompetent to give informed consent. As human subjects, children are especially vulnerable. The following definitions are important for research with minors: (a) "Children" are 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. (b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research. (d) "Parent" means a child's biological or adoptive parent. (e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

The IRB has decided that written assent should be obtained from children aged 12 and older; verbal assent should be obtained from children under 12 years of age. Assent from a child should be requested only after the child's parents or guardians have agreed that the child may participate. In most cases, the signature of one parent or guardian is sufficient. However, in studies involving greater than minimal risk, signatures from both parents or guardians may be required.

Information provided during the procedure to obtain consent or assent from children should be presented in a form understandable by the children selected for the study. We encourage researchers to consider alternatives to the conventional consent form used with adults. Appropriate alternatives include: a checklist, pictures, role playing and audio-visual methods. The basic information about procedures, purpose, selection, risks, benefits and willingness of the researcher to answer questions should be provided to children serving as research subjects.

Oral consent

In certain cases, the Principal Investigator may determine that oral consent is more appropriate and more adequately safeguards the subject. The oral consent form shall consist of a written consent document presented orally to the subjects (or his/her legally authorized representative). The IRB shall approve the written text of what is said to the subject or representatives. A copy of the information that is read to the subject should be given to the subject or the representative to keep. There should be a witness to the oral presentation who can attest that the information was given as stated.

When it might be appropriate to omit the use of a consent form

As a general rule, the IRB believes informed consent should be obtained from all research subjects. However. if the Principal Investigator believes that obtaining a signed consent form would be inappropriate, such a request must be justified according to the following criteria:

1. The only record linking the subject and the research would be the consent form and the principal risk would be potential harm resulting from a breach of confidentiality.

2. The research presents no more than minimal risk and involves no procedures for which written consent is normally required outside the research context. For example, in a sample survey of volunteers, investigators would describe the nature of the interview to the subjects. Rather than seek written approval, participation here is regarded as de facto consent.

3. Tacit Consent. When participation entails only the completion of anonymous written questionnaires, consent may be considered to be tacit. Provided that responses can in no way be used to identify subjects, written consent is not necessary. (To ensure that participation is voluntary, the investigator should not be present when subjects are filling out the instruments and subjects must not be required to hand back their responses directly to the investigator.)

When the use of a consent form is waived, the IRB requires the Principal Investigator to provide subjects with a written statement regarding the research.

Signatures: Student researchers must obtain the signature of their faculty advisor before the IRB will consider their application.

Reporting Unanticipated Problems and Changes in Protocol: Any unanticipated problems involving risks to subjects or others participating in a research study, or proposed changes to a previously approved application must be promptly reported in a written memorandum to the IRB. This includes changes in the (approved) consent form, sample composition, sample recruitment, or study procedures.

Applicants Seeking External Funding: Federal regulations require that protocols be "tracked" to grant proposals, although IRB review and grant proposal preparation are independent activities.

FREQUENT OVERSIGHTS IN APPLICATION MATERIALS AND CONSENT FORMS

1. The language in the consent form must be understandable to the population being addressed (e.g., children). In the event that consent forms may be best understood in another language, that version must be submitted along with an English translation.

2. The name and status of the investigator, as well as the University, school and department identifiers should be incorporated into the consent form text. The address and telephone number where the researcher can be reached should questions arise also must be included; where appropriate, the name of and telephone number of a faculty advisor should be included as well.

3. When cooperating institutions are involved, a letter of cooperation from an authorized official should be included. If a letter is not available at the time of application, it must be submitted before research may begin.

4. Methods for maintaining confidentiality of the data should be described in detail (i.e., coding procedures, who has access to the files, where files are kept, and how anonymity is protected).

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5. When treatment or services are involved, an affirmation should be included indicating that an individual's decision not to participate will in no way affect the availability of services to which individuals are entitled.

6. When students are involved, an affirmation should be included indicating that non-participation will in no way affect academic standing.

7. When children are involved, both parental permission and children's consent or assent are required.

8. When video or audio taping is involved, an opportunity to review the completed tape must be given so that subjects may ask that it not be used (either in whole or in part).

9. Requests to have proposals classified as exempt must be accompanied by a supporting statement, detailing which category of exemption is being claimed, and why the researcher believes the activity falls into this category. In the case of minors (individuals under 18 who are participants in research), exemptions are limited to the following categories of research:
   a) studies that constitute normal educational practices in educational settings;
   b) educational tests, where identifiers are not recorded;
   c) collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available, or if the information is recorded so that subjects cannot be identified.
   d) observation (as opposed to participation) by the principal investigator of public behavior where identifiers are not recorded by the principal investigator and there is neither a risk of harm to subjects nor observation of sensitive aspects of the subjects' own behavior.

LSU EUNICE INSTITUTIONAL REVIEW BOARD
APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH

Please note: Step-by-step instructions and other information relevant to filling out this form are contained in LSU Eunice's Principal Investigator's Manual for Research involving Human Subjects. All investigators are expected to be familiar with the policies and procedures it contains. Failure to follow the instructions may result in a delay in the approval process.

1. Project Title: _____
   (see page 3 of Manual)

2. Principal Investigator: _____

   Department: _____Phone: _____Fax: _____Email:_____
   (see page 3 of Manual)

3. Co-PI (if any) _____

   Department: _____Phone: _____Fax: _____Email:_____

4. Status (check one): Faculty _____
   Undergraduate Research _____
   Other (please explain) _____

5. For students and non-LSU Eunice researchers only, please give your home address and phone number:

   _____

   _____

   Faculty Advisor: _____

   Department: _____Phone: _____Fax: _____Email:_____
   (see page 3 of Manual)

   NOTE: The IRB will not review protocols submitted by students without the signature of a faculty advisor on page 5 of this application.

6. Type of review requested: _____ Exempt _____ Expedited _____ Full IRB
   (for an explanation of the three types of review, see pages 3-6 of the Investigator's Manual):

7. Does your study involve the collection of data from a vulnerable population? ____yes _____no

   If yes, please specify: _____

For a complete list of categories of vulnerable populations, as well as the special safeguards required when conducting research with them, see page 6 of the Investigator's Manual. Special Informed Consent procedures are necessary when conducting research with minors. See pages 12-13 of the Manual for information.

8. Does this study involve deception (research in which the subject is purposely lead to have false beliefs or assumptions)?. _____yes _____no
(see page 6 of the Investigator's Manual)

9. If the study involves risk to subjects, is the risk greater than that incurred in ordinary life or tasks?
_____ yes _____ no
(see page 7 of the Investigator's Manual)

10. Has this study ever been previously approved by the IRB? _____ yes _____ no
(see page 7 of the Manual)

11. Check if this proposal is _____ new or _____ revised in response to previous IRB review.
(see page 7 of the Manual)

12. Is funding being sought for this study? If yes, through what sponsoring agency?

_____
(see page 7 of the Manual)

13. Is this study being reviewed by an Institutional Review Board at another institution? If yes, please list cooperating institutions below and attach an official letter of cooperation. (see page 7 of the Manual)

_____ _____

Documentation of IRB reviews of this study conducted at other institutions must be provided when it becomes available. Research may not begin until IRB review has been concluded at all institutions involved.

For EXEMPT reviews, submit original and 1 copy of this APPLICATION.

For FULL IRB reviews, submit original and 6 copies one month before approval is needed.

The IRB may meet once per month from September through May.

Please submit all applications to the Vice Chancellor for Academic Affairs.

Special Deadline Information is contained on page 7 of the Investigator's Manual

EXEMPT REVIEW

Requests for exemption from IRB review must include the information requested below. If exempt status is granted, the study will no longer be under the jurisdiction of the IRB, unless procedures are revised which deviate from those originally reviewed by the IRB. Research involving protected populations, e.g. prisoners, pregnant women or fetuses, is not eligible for exempt status.

Exemption may be claimed under the following categories: (for complete description of these categories, see p. 4 of the Investigator's Manual)

1. Research involves the study of normal educational practices in commonly accepted educational settings.
2. Research involves the use of educational tests, surveys, or interviews where identifiers are not recorded by the PI or where there is neither a risk of harm to subjects nor information sought concerning sensitive aspects of the subjects' own behavior. Research involves observation of public behavior where identifiers are not recorded by the PI and there is neither a risk of harm to subjects nor observation of sensitive aspects of the subjects' own behavior. This exemption does not apply to research with children when the investigator[s] participate in the activities being observed; for example, in classroom situations where the researcher is taking part in the classroom activities being studied or surveys and interviews with children.
3. Research involves the use of educational tests, surveys, interviews, or observation of public behavior that is not exempt under the above category if: (a) subjects are elected or appointed public officials or candidates for public office or (b) 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 involves merely the collection or study of existing data, documents, records, pathological or diagnostic specimens, where publicly available or where the information is private by identifiers not recorded by the PI.
5. Research to examine current public benefit or service programs, or alternatives to existing programs.
6. Taste and food quality evaluation and consumer acceptance studies, if food or additives consumed meet FDA safety standards.

I believe my research can be classified as exempt under category number(s) _____ above.

PI Signature _____ Date _____

Co-PI Signature _____ Date _____

Faculty Advisor's Signature _____ Date _____
(required for student research)

Please append to this document a description of your research sufficiently detailed to justify exemption under one or more of the above categories. (For more about this description and what it should contain, see page 8 of the Investigator's Manual) Final judgment on exemptions rests with the IRB.

You will be notified if your study is found to be exempt from further IRB review.

FULL IRB REVIEW

Please consult pages 8 of the Investigator's Manual for an explanation of expedited and full IRB review and the types of research which may be reviewed under each procedure. Request for expedited review may be referred to the full IRB if the Chair of the IRB deems it appropriate.

Please answer the following questions on a separate sheet and attach to application form:

1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study and indicate whether it has received IRB approval from another institution (see p. 8 of the Investigator's Manual). Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.

2. Describe the source(s) of subjects and the selection criteria. Selection of subjects must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. (See pages 8-9 of the Investigator's Manual for a discussion of equity in subject selection and page 6 of a discussion of protected populations). The text of any advertisement, letter, flier, oral script or brochure used to solicit potential subjects must be attached.

3. Provide a description of the procedures to be followed. If available, include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of subjects' involvement. (See p. 10 of the Investigator's Manual)

4. Describe any potential harms or benefits to be derived by subjects, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety. (See p. 10 of the Investigator's Manual)

5. Describe the specific methods by which confidentiality and anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed. (See p. 11 of the Investigator's Manual)

6. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition. (See p. 11 of the Investigator's Manual)

Upon approval of the study, the consent document will be stamped with an expiration date. Only this document may be used when enrolling subjects. Studies extending beyond the expiration date must be submitted for a continuation review. Any changes in the consent form must be approved by the IRB.

7. Before submitting this application, all investigators should familiarize themselves with the discussion of informed consent contained in pages 11-12 of the Investigator's Manual. Describe

the oral and written consent processes and attach all consent documents, including scripts for oral consent and assent form for research involving minors under the age of 12. When the consent form to be used will be in a language other than English, an English translation must be provided. Unless one or more of the required elements described below is explicitly waived by the IRB, informed consent documents should contain:

a) A fair explanation of the procedures to be followed and their purposes, including any procedures that are experimental.
b) A description of any possible attendant discomforts and risks reasonably expected.
c) A description of any benefits reasonably expected.
d) A disclosure of any appropriate alternative procedures.
e) An offer to answer any inquiries concerning the goals of the research or the research procedures and to provide a summary of results upon request. A contact person and phone number should be provided.
f) An instruction that the subject is free to withdraw or discontinue participation at any time without prejudice.
g) A statement that the data are confidential and that the subject will not be identified by name in writing or orally.
h) Provisions for parent or guardian approval for participation of minors or for subjects from vulnerable populations when appropriate.

8. Please provide any other information that might be pertinent to the IRB's decision.

All applicants: I agree to use procedures with respect to safeguarding human subjects in this activity that conform to University policy. If significant change in investigative procedure involving human subjects is called for during the activity covered by this application, I shall seek prior approval for such change from the IRB and agree to follow the advice of the IRB. The faculty sponsor's signature indicates that s/he has reviewed this application and accepts the responsibility of insuring that the procedures approved by the IRB are followed.

PI Signature _____ Date_____

Co-PI Signature _____ Date_____

Faculty Advisor Signature _____ Date_____
(required for student research)

For applicants seeking external funding only:
I certify that the research plan and safeguards to human subjects described in this application conform to that which has been submitted/will be submitted to an external funding source.

PI Signature _____ Date_____

Co-PI Signature _____ Date_____

Grants Officer Signature _____Date_____

Name of Sponsor _____Internal Reference #_____
Before submitting this form, consult page 14 of the Investigator's Manual, "Frequent Oversights".