



LSUHSC-NO Institutional Review Board
Federal Wide Assurance 00002762 IRB Registration # 00000177

Information Sheet - Expedited Review Requests

The information provided offers definitions and explanatory remarks regarding the items for the Application -----**Expedited Review Request**-----

This document is not a fillable form

Item 1 Investigators

List the Principal Investigator and other Investigators by name. Department information and training, etc. is listed in the Demographic Form. This is to identify the project and to link it to the Demographic Form.

Item 2 Title

Titles on all parts of the application must be identical.

Item 3 Categories for Expedited Review

The federal regulations allow for expedited review under 45CFR46.110(b). Select the categories that apply to this protocol.

Item 4 Project Abstract

The writing style should be similar to that used in popular science and news magazines such as Smithsonian and National Geographic. Other examples of abstracts can be found at PubMed. No more than 300 words.

Item 5 Project Summary

Items can be listed in bullet style

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. Provide a summary of research reported in the literature that forms the scientific background for the present study.

Objectives: List your research objectives and goals.

Study Design: Describe the study design (e.g., control and experimental groups, qualitative, quantitative, focus group, etc.). Indicate whether subjects will be randomized for this study. Address whether deception will be an element in the study.

Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify eligibility by listing the inclusion and exclusion criteria. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, decisionally impaired, prisoners or others who are likely to be vulnerable. If women or minorities are excluded, provide written justification.

Subject Recruitment Methods: Describe plans for the recruitment of subjects. Specify if any advertising will be performed. If yes, attach copies of the flyers, posters or advertisements. Advertisements must be reviewed and approved by the IRB prior to use.

Informed Consent Process: Describe the consent procedures to be followed, including how the population will be accessed, the circumstances under which consent will be sought and obtained, who will seek consent, and the method used for documenting consent. Describe, if applicable, use of specific instruments or techniques to assess and confirm potential participants' understanding of and decision-making capabilities.

Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. If applicable, differentiate between procedures that involve standard/routine procedures for care/treatment from those which will be performed specifically for conduct of this research project.

Potential Risks: Describe any potential risks, i.e., physical, psychological, social, legal or other, and assess their likelihood and seriousness. Where appropriate, describe alternative treatments or procedures that might be advantageous to the subjects.

Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Risks can be emotional and psychological as well as physical. Where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. Individuals must be advised that they do not have to respond to written or verbal questions that make them feel uncomfortable.

Benefit vs. Risks: Discuss why the risks to subjects are reasonable in relation to the anticipated benefit to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

Alternatives: Describe alternative procedures that might be available to subjects who choose not to participate in the study. This could be fee-for service weight-loss clinics, physical therapy clinics, nutritionists, or free parenting classes, addiction support groups, bereavement groups, etc.

Research Materials, Records and Confidentiality: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records or data. This includes responses to questionnaires or surveys, medical

histories, records and diagnoses. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data. State the mechanisms for maintaining confidentiality and data security.

Definitions for use in filling out sections in the application

-- Identified data or samples.

This means samples or data that are still attached to a readily available subject identifier such as a name, social security number, address, telephone number, medical record number, etc.

-- Coded.

This means that collected samples or data are unidentified for research purposes by, for example, the use of a random or arbitrary alphanumeric code but the samples may still be linked to their sources through the use of a key to the code available to an investigator or collaborator.

--Unlinked.

This means that human data or samples that were initially collected with identifiers but, before research use, have been **irreversibly** stripped of all identifiers by using an arbitrary or random alphanumeric code and that the key to the code is destroyed. You may still use links to existing demographic, clinical, and pathological information before the subject identifiers are removed.

--De-identified Definition under Privacy Rule

A de-identified data set is one in which either: (1) The 18 identifiers specified in 164.514(b)(2)(i) have been removed and the covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify the individual (safe harbor method); or (2) a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, determines the risk is very small that the information could be used by the recipient, alone or in combination with other reasonably available information, to identify an individual (section 164.514(b)(1)), and documents the basis for such determination. A de-identified data set is not protected by the Privacy Rule and may be used and disclosed without restriction.

--Anonymous

Samples or data were collected without identifiers of any kind. Information collected in this way may retain demographic or diagnostic information and still be considered unidentified if such information cannot be used to reveal the identity of the source.

Compensation for Participation: Describe the compensation being offered to subjects for their time and expenses during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms of payment. It is IRB policy that provision should be made for providing partial payment to subjects who

withdraw before the completion of the research. Monetary payments should be prorated and paid at the time of each visit. Also, describe any costs which will be accrued by the subjects as a consequence of participating in the research.

Data Safety and Monitoring for Research: Provide a plan to ensure the data safety and monitoring of the proposed study. The National Institutes of Health policy requires that grantees have in place procedures for data safety monitoring of clinical trials. The IRB is required to review and approve the data safety monitoring plans. For NIH funded clinical trials, include a description of the Data Safety Monitoring Plan.

Item 6 Subjects

In the evaluation of the risk/benefit, the IRB must consider the subject population that will participate. Indicate the number of subjects and the type of subjects.

Item 7 Recruitment – List the methods that will be used. All letters, fliers, and requests to identify, solicit or recruit subjects must be provided with the application.

Item 8 Informed Consent Process and Documentation

In this section provide the names of study personnel who will provide informed consent. In addition provide the specific location(s) where informed consent will take place such as Touro Hospital Nurses lounge, Ochsner Hospital Women’s Pavillion, etc.

Item 9 Confidentiality and Anonymity

Confidentiality of data must be considered carefully. Access to data must be limited especially when sensitive data is being collected. Laptops can be stolen, also cars where the lap top may be living. Handwritten forms, yellow legal pads and documents can get mixed up with non-research documents.

Talking about the subjects in a study even with other professionals may not be appropriate. Discussing specific subjects, data and interesting or astounding anecdotes with non-study personnel could be a breach of confidentiality.

Item 10 After Completion of Data Collection

Fill this information in as completely as possible to help you in your plan for research data integrity. Provide the IRB with the information on how and where data will be stored. How long the data will be kept is also of concern.

Item 11 Waiver of HIPAA Authorization

Health Insurance Portability and Accountability Act of 1996 (HIPAA)
HIPAA Authorization is required for all research studies that collect protected health information. The Privacy Rule contains criteria for waiver or alteration of the Authorization.

The LSUHSC-NO IRB will determine if all the criteria have been met.

Item 12 Waiver of Informed Consent

Informed Consent is required when conducting human subjects' research. 45CFR46.116

The federal regulations do allow a waiver or changes under certain criteria. Those criteria are listed in this section on the application. They must be answered relative to the procedures in your study. 45CFR46.116(d)

Item 13 Waiver of Documentation of Informed Consent

45CFR46.117(c)(1)or(2) provides criteria under which a waiver of written consent or other alteration may take place.

If a waiver of written documentation is requested for this protocol it must be provided here.

Waiver information is also provided as a separate form.

For Submission

The Application for Expedited Review must be printed and submitted with all of the necessary and supporting documentation. Incomplete submissions may result in delay of processing.



Expedited review procedures can be considered when research activities:

1. Present no more than minimal risk to human subjects, and
2. Involve only procedures listed in one or more of the categories for new studies.

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 1-7 apply regardless of the age of subjects, except as noted.

Researchers are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) also apply to expedited review.

Minimal Risk: "the probability and magnitude of harm or discomfort anticipated in the 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" [as defined by 45 CFR 46.102\(i\)](#).

When making a decision about minimal risk of research:

1. **Consider both magnitude and likelihood of risk**
A more serious event may be permissible if its probability is extremely low;

Example: There is the risk of death in attending a large gathering such as Jazz Fest, however the likelihood of that is extremely rare.

2. **Risks of ordinary, non-invasive diagnostic tests are OK**

Examples: routine blood draws in adults, general physical exams, pen-and-paper tests, ultrasound exams(at accepted levels)

3. **Minimal risk may be age- or context- dependent**

Example: Blood draw may be minimal risk for someone old enough to give consent, but not for a small and needle-shy child

4. **Remember that risks need not be "physical" in order to be "more than minimal"**

Examples: A serious privacy risk, confidentiality risk, informational risk or risk of embarrassment may be enough to push a study into the "greater than minimal risk" category and thus to full committee review

When Expedited Review Categories do not apply

- 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.
- The expedited review procedure may not be used for US government classified research involving human subjects.

NOTE: When submitting an application draft documents, tools, or survey forms cannot be accepted. Only the final version of items will be accepted.