



Institutional Review Board Policies and Procedures Guidebook LSU Health Sciences Center New Orleans

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1.0 FEDERAL, STATE, AND UNIVERSITY REGULATIONS RELATED TO THE IRB

The IRB is guided by ethical principles established by the World Medical Association, and its adoption of the Declaration of Helsinki, the Belmont Report and by the Ethical Guidelines of Behavioral Research of the American Psychological Association. These principles are implemented in consonance with applicable university, state and federal laws and regulations. Review is required for all research and related activities involving human subjects conducted by investigators with an appointment (hereafter referred to as employee) at LSUHSC-NO, as established by federal law.

LSUHSC-NO conducts its research and IRB oversight in compliance with the following federal regulations:

- The Code of Federal Regulations related to the Office for Human Research Protections authority (45 CFR 46, Subparts A-D) which is available on the World Wide Web at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- The Code of Federal Regulations related to the Food and Drug Administration <http://www.fda.gov> authority (Title 21 CFR Parts 50, 56, 312, 600 and 812.66) which is available on the World Wide Web at <http://www.gpoaccess.gov/cfr/index.html>
- The Federal Wide Assurance that LSUHSC-NO has adopted can be viewed at the OHRP website at <http://www.hhs.gov/ohrp/>. Note that through this document, LSUHSC-NO has extended its assurance to include all human subjects research, independent of the sponsor of the activity.
- The OHRP IRB Guidebook is available from the OHRP website at <http://www.hhs.gov/ohrp/> and provides information regarding IRB activities and responsibilities. Other important information related to human subjects protection, including the Belmont Report, can also be found at the OHRP website.

Approval of any submission to the IRB is contingent upon meeting all of the requirements of 45 CFR 46 (Subparts A-D) and where appropriate 21 CFR 50, 56, 312, 600 and 812 including all operative Subparts. Submissions must also comply with all state and local requirements and laws. Policies and procedures of the LSUHSC-NO IRB are described in the following chapters. All of these regulatory documents must be understood and adhered to by all investigators.

It is the policy of LSUHSC-NO that all projects involving human beings and/or information or tissue collected from human beings must be presented to the IRB for a determination whether:

1. The project is human subjects research,
2. The human subjects research project can be given Exempt status under the regulations, or
3. The human subjects research project must have IRB review, approval, and continued oversight.

If you require additional assistance call the IRB office at (504) 568-4060.

2.0 RESPONSIBILITIES AND FUNCTIONS OF THE HEALTH SCIENCES CENTER ADMINISTRATION

2.1 Administration of the IRB

The administration of the LSU Health Sciences Center has delegated to the IRB the full authority of the Chancellor's Office for the conduct of the program. The Vice Chancellor for Academic Affairs will exercise such functions that require official action. The day-to-day conduct of the program will be the responsibility of the Chair or Vice-Chair of the IRB. Specifically the administration shall:

- A. Maintain active files for all investigators submitting protocols to the IRB for approval
- B. Ascertain that all proposals are screened relative to the need for the IRB evaluation
- C. Provide necessary support services for the IRB
- D. Transmit to Department of Health and Human Services (DHHS) all actions on DHHS supported activities
- E. Make certain that all recommended actions are initiated pursuant to IRB decisions
- F. Present appropriate and ongoing educational opportunities for IRB staff, Board members, investigators and others, concerning human subjects protection, related federal regulations and IRB procedures and policies
- G. Make certain that the professional staff is informed as to the responsibilities of the institution for protection of human subjects
- H. Develop necessary arrangements with affiliated and other institutions for mutual assurance of protection of human subjects
- I. Implement FDA regulations and transmit reports regarding investigational new drugs and devices
- J. Provide the liaison and channeling of appropriate information between staff, IRB, the administration, and governmental agencies
- K. Exercise a continuous surveillance of the IRB program by:
 - 1. Reviewing all grant applications and clinical trials and research agreements to determine that IRB review has been instituted where required
 - 2. Maintaining permanent files on IRB actions
 - 3. Reviewing IRB activities to make certain that the guidelines are being implemented

2.2 IRB Disapproval

IRB disapproval cannot be overruled by the Health Sciences Center administration. However, approvals may be overruled. Project directors or principal investigators (PI) may appeal disapprovals or restrictions on approvals to the IRB. If the PI wishes to further challenge any decisions made by the IRB, the PI may initiate the process through the administrative official, the Vice Chancellor for Academic Affairs.

2.3 Research Funding

Funds for studies may be withheld at the discretion of the administration.

3.0 THE INSTITUTIONAL REVIEW BOARD

3.1 IRB Authority

The Board is designated as the Institutional Review Board (IRB) and is responsible for reviewing all research projects involving the use of human subjects to determine that (a) the risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained, as to warrant a decision to allow the subject to accept those risks; (b) the rights and welfare of the subject are adequately protected; and, (c) legally effective informed consent is obtained by adequate and appropriate methods. As defined by federal regulations, IRB authority extends to any study using live human subjects, or data, or tissue collected from live humans. It is also an institutional policy that IRB approval must be obtained to collect and use in a study any tissue collected from a cadaver when that individual had been identified before death as a person from which tissue was needed for a research study.

The IRB interacts directly with the departmental heads and center directors of the schools within the Health Science Center. Principal investigators must contact their departmental head before submitting an application to the IRB. The IRB accepts applications from the principal investigator only after signature of the departmental head or center director is obtained. The departmental head or center director's signatures verifies that: (a) the principal investigator has permission to conduct the study if approved, (b) that the IRB application, protocol, and related documents have been reviewed and are recommended for submission to the IRB, (c) that the principal investigator has the expertise to conduct the study, and d) that the principal investigator is an employee in good standing at LSUHSC-NO.

The Board reviews all human research activities conducted only by employees of LSUHSC-NO. Student-conducted (student, fellow, resident, and others in training without a faculty appointment) research must be supervised by an LSUHSC-NO faculty mentor. The IRB application must be submitted by that mentor who will assume the role and responsibilities of principal investigator. The approval is given to the principal investigator (faculty mentor).

Any research that involves human subjects conducted by LSUHSC-NO employees (both full and part-time) regardless of the location of the study must be evaluated and approved by the LSUHSC-NO IRB before initiation of the project. For example, if studies are to be performed at other institutions, all LSUHSC-NO employees must apply to the LSUHSC-NO IRB even if their participation is limited to co-investigator or other roles. Approval by the LSUHSC-NO IRB for its employees does not extend to individuals on the project who are not LSUHSC-NO employees. Those individuals must seek IRB review from their IRB of record. LSUHSC-NO IRB is the IRB of record for all of its employees (both full and part-time). Prior to initiation, any human subjects research conducted by Gratis faculty in LSUHSC-NO facilities or through an award made to or contract with the Institution must also be evaluated and approved by the LSUHSC-NO IRB.

Categories listed as exempt by the federal regulations must also be submitted for review and approval by the IRB. The Board has the authority to require progress reports from the investigators and may take any other action it deems appropriate to oversee the conduct of any study. While approval of an IRB application is given in the principal investigator's name, it should be understood that all investigators of the study have a responsibility to be sure that all IRB policies and procedures are adhered to during the conduct of the study.

Except as described in [Section 4.10](#) of this "Guidebook" for Cooperative Group Studies, LSUHSC-NO is unable to accept IRB review by other institutions in lieu of the LSUHSC-NO's IRB review. Reciprocity of IRB review is not permitted by this institution.

To assure compliance with all policies and regulations, the Board, following a thorough investigation, may take actions against any or all investigators listed on the study including but not limited to warning, reprimand, censure, or suspension and prohibition from conducting human subject research at LSUHSC-NO and its facilities.

Any policies and procedures governing the IRB may be changed at a convened meeting. These changes require a vote by a majority of the Board members present based on a quorum.

The IRB, through the Vice Chancellor for Academic Affairs, interacts with all governmental agencies.

3.2 Responsibilities of the Board

The IRB is charged with the duty of making certain that all activities involving human subjects conform to the following guidelines:

- A. The activity is based upon established and accepted procedures.
- B. The activity is conducted or supervised by a properly qualified individual.
- C. The activity is planned to include a critical evaluation of the possibility of risk or harm (physical, physiological, sociological or others, including invasion of privacy) as the consequence of this activity. The rights and welfare of the subject must be adequately protected, based on the above evaluation.
- D. The activity must have an objective that risks to the subject are so outweighed by the sum of the benefits to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept those risks.
- E. The activity can be initiated only after informed consent is obtained from the subject(s), documented by adequate and appropriate methods. These are delineated in the application form instructions.
- F. Any activity that does not conform to all state and federal guidelines or IRB required procedures is subject to termination by the Board.

- G. The activity must have sufficient scientific merit in the field of research to allow subjects to participate.

3.3 The Composition of the IRB and Quorum

In order to promote complete and adequate review of research and research related activities the IRB is comprised of 11 Primary, voting members with diverse backgrounds. IRB members representing a variety of professions and disciplines to assure appropriate expertise are available to evaluate applications. Alternate members may substitute for a Primary member, for which they are designated if a Primary member is not present or is recused. In this case, the Alternate member may vote, otherwise an Alternate may attend the meeting but may not vote on any action.

All members are appointed by the Chancellor of LSUHSC-NO. The Board is comprised of both males and females and at least one member is an individual whose primary expertise is in a nonscientific area. At least one member is not an employee or a part of the immediate family of a person affiliated with the institution.

A quorum of the Board is defined as a majority of the membership. Alternate members attending the meeting in a non-voting capacity do not count toward a quorum. No member may participate in the initial or continuing review of any project in which the member has a conflicting interest except to provide information requested by the Board. Members with conflicting interests will leave the meeting room during the deliberations and voting on said project. At least one physician member must be present when considering FDA regulated articles. At least one member whose primary interest is in a non-scientific area must be present. Members must be present to vote. A majority of the membership present must vote in the affirmative for a motion to pass.

Information about the Board membership is available from the IRB office, 568-4060.

3.4 IRB Member Duties

The members are required to familiarize themselves with and to evaluate all applications (new and re-approval), amendments, and adverse events provided in the agenda book which is supplied to them prior to the IRB meeting.

Members acting as primary reviewers are required to evaluate all applications, amendments and adverse events assigned to them by the Chair. Evaluation Forms are distributed to assist the members in performing their assessments. The forms must be completed prior to the meeting. During the meeting the IRB member assigned as primary reviewer for an action item is expected to present their assessment and to lead a discussion of the Board concerning the item under consideration. All members are expected to contribute to a thorough discussion of all items. The primary reviewer should present a motion for consideration.

Members may also be needed for their expertise to evaluate special concerns that may arise on any study.

Committees of the Board are utilized for special concerns, e.g. consideration of new policies, issues of non-compliance, etc. The committee members are appointed by the Chair based on the required expertise for the issue at hand. Committee reports are presented for consideration by the fully convened Board.

No member of the IRB may participate in an initial or continuing review of any project in which the member has a conflict of interest; except to provide information to the IRB. Should a conflict of interest exist, the member is responsible for notifying the IRB office one-week prior to review. A member with a conflict of interest must recuse themselves from the meeting during deliberation and voting on the item.

Members are expected to familiarize themselves through educational opportunities provided by the Institution with regulations and policies and procedures related to IRB function and with issues surrounding human subject protection.

The institution also supports the members of the IRB through the following:

1. Liability coverage for all IRB members is provided by the Institution.
2. Reference materials are available in the IRB office for members or principal investigators to assist in the review and/or preparation of applications.
3. Educational opportunities and materials related to IRB function and human subjects protection.

The IRB does invite individuals who are not members to serve as expert consultants for review of selected applications. These consultants serve in a non-voting, advisory only capacity.

3.5 The IRB Chair

The daily responsibility for the management and operation of the Board and the IRB Office is vested in the Chair. The Chair is selected and appointed by the Chancellor of the LSUHSC-NO. The Chancellor retains the sole authority to remove the Chair. The Board has designated one member to serve as Vice-Chair. The Vice-Chair has the full authority to act for the Chair in his/her absence.

A. Authority

1. Calls emergency sessions as needed
2. May require study modifications which can include suspension of enrollment when risks/complications arise that significantly endanger the subjects until discussion by the full Board
3. Requests files, reports, and additional data from principal investigators when the need arises

4. May require principal investigators to appear before the IRB when questions arise about any study
5. Votes as a member of the IRB
6. May approve responses to applications submitted to the Board that resulted in a vote of Modification Required to Secure Approval. Consultation with another Board member(s) may be necessary
7. May approve minor modifications to ongoing protocols with possible agreement by another Board member(s). These are modifications that do not significantly affect the risk to the subject
8. May conduct an expedited review procedure as defined in federal regulations and exercise all of the authority of the IRB except disapproval
9. Presides at all meetings when present
10. Signs all official notifications from the Board

B. Responsibilities

1. Schedules monthly meetings
2. Sets the agenda for monthly or called emergency meetings
3. Provides for the distribution of the meeting agenda and meeting book that includes all of the study materials to be considered at the meeting
4. Provides for the taking of minutes, duplication of minutes, and distribution of minutes to IRB members in a timely fashion
5. Distributes literature to IRB members regarding the concerns of the IRB
6. Keeps an updated file on all studies submitted to the IRB
7. Maintains a file of curriculum vitae for all members of the Board

4.0 Operating Procedures of the IRB

The functions of the IRB include conducting initial and continuing review of all human research activities conducted at LSUHSC-NO. The Board also conducts evaluation of all amendments, revisions, changes, advertisement for subjects, adverse events and special situations brought to the attention of the Board or the Chair or Vice-Chair, or any member. For all of these actions, the communication to the IRB office must be signed by the principal investigator.

4.1 Criteria for IRB approval of research. (45 CFR 46.111 and 21 CFR 56.111)

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- A. Risks to subjects are minimized
 - 1. By using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - 2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
- B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- C. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45CFR46.116.
- E. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45CFR46.117.
- F. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- G. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- H. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

4.2 Conducting Review of New Applications

Preparation instructions for submitting applications are contained in the Application Instructions. Information regarding investigational new drug (IND) and investigational device exemption (IDE) submission requirements are also included in the instructions.

New applications are accepted throughout the month. However, the DEADLINE for submission of any new application that requires full Board review is the last working WEDNESDAY of the month to be eligible for the next month's meeting.

Upon receipt of a new application, the IRB office date-stamps and assesses the application for completeness. Waiver of the consent form may be granted at the investigator's request if all federal regulations apply (see [Section 5.5](#)). It is recommended that the investigator contact the IRB office prior to submission to discuss these regulations. The PI will be contacted for additional information and/or incomplete data. It must be understood that if the application is incomplete and is received immediately prior to the deadline the application may be ineligible for that review cycle. Consequently, it is very important for the PI to make certain that the application and all required material are complete before submission.

Also upon receipt of a new application an IRB Tracking Number is assigned for that protocol. A paper file is created as well as an electronic file in the IRB management, software. These two files, paper and electronic, comprise the official record for the study. All future correspondence with the IRB must reference that number. Correspondence that does not identify the IRB number will be returned without further action.

All new applications are evaluated by the Chair or designee to determine if they are eligible for expedited review according to 45 CFR 46.110 and 21 CFR 56.110. Applications qualifying for expedited review procedures must have an appropriately formulated consent form depending upon the degree of risk unless a waiver is requested. The consent form is evaluated and corrections are required by the Chair or his designee prior to approval. Applications for exemption are evaluated by the Chair or designee to determine if they are eligible for consideration under 45 CFR 46.101 b. and/or 21 CFR 56.104. The process of notification and receipt of investigator assurance is identical to full-board considered projects.

Each application requiring full-board review is assigned a primary reviewer by the Chairman or Vice-Chair(s). New applications are slated for a specific agenda. In addition to the application and consent form the primary reviewer receives the expanded protocol and all other related materials. The remainder of the Board

receives the application that includes the project summary and the proposed consent form. All other material including the full protocol is available to all members both before and during the meeting at which the application is reviewed.

The application is reviewed at the next scheduled meeting. The Board evaluates each proposal with a full discussion on the merits of the full protocol. These include but are not limited to scientific merit, risks/benefit ratio to subjects, expertise of the investigator, etc. Particular emphasis is placed on the risks to subjects that may be encountered as a result of enrollment in the protocol. These risks may include but are not limited to medical, psychological, financial and social risks. To properly prepare the protocol for the review, the investigator must consult the Instruction Guide to Completing the Application Form.

During the meeting, the primary reviewer presents a summary and leads a discussion of the study. The primary reviewer then makes a recommendation based on the review of the full protocol, application, consent forms, investigator's brochure, related federal grant application, and any other related material. A motion is made and seconded, members are asked for comment, and the Chair calls for a vote. The vote is recorded on the Chair's vote sheet. Notification of the Board's decision is made to the principal investigator following the meeting.

Potential recommendations from the Board are:

Approval: No further changes needed

Modifications Required to Secure Approval (MRSA): Moderate revisions are necessary. The modifications in the study provided in response to Board concerns will be reviewed in the IRB office by the Chair or Vice Chair to assess that changes have been incorporated. The Chair may seek assistance of any member of the Board for this process. In most cases these modifications will not have to be re-assessed by the full Board. However, if the Chair or any other Board member is not satisfied with the quality of the response it will be re-assessed by the full Board at an officially convened meeting.

Withheld: Extensive revisions needed. Modifications must be re-submitted for Full Board Review. In order to be assessed at the next meeting, changes will have to be in the IRB office by the last working Wednesday of the month. The time frame for return of the response may be short if the investigator wishes to have the application re-evaluated at the next scheduled meeting. The investigator should be prepared to attend the meeting to discuss his/her application if so requested by the Board.

Disapproval: The scientific or ethical problems posed by the study are of grave concern to the Board. The proposal cannot be re-submitted "as is". A new proposal must be submitted to the Board. Minor modification would not be appropriate to resolve these issues.

4.3 Notification of Investigators Following Review

The IRB office notifies each investigator in written memo form (see example in Forms Section) of the review of their submission. The memo will outline the necessary actions and upon receipt of that memo the PI makes the required corrections, modifications, or resubmits a new application. If a response is not received within the time noted on the letter the application will be rescinded. This would require a complete new application package to be submitted for consideration by the Board at a future meeting if the PI wishes to pursue the study.

4.4 Investigator Assurance and Notice to the Institutional Official

When the protocol receives final approval, the IRB office generates an approval notice, which is addressed to the Vice Chancellor for Academic Affairs (the Institutional Official).

Two copies of this notice are prepared and the Chair or Vice-Chair signs both. The notice is sent to the PI, who must then countersign the assurance document. One copy is retained by the investigator for their files and the other returned to the IRB office. This document is included in the Forms Section. The original of the signed assurance is kept in the protocol file for that project and a copy is forwarded to the Vice Chancellor for Academic Affairs. The IRB office also forwards a signed, stamped copy of the first page of the approved consent form.

The period of approval is determined by the Board based on the merit of the study and the level of risk to the subject. The duration of the approval period is tracked through a computer database. The period of approval is included on the form and will not exceed one year. The initial approval period will begin the date of the meeting at which the application was approved. If the determination that a period of less than one year is required, the IRB may set any time period as the appropriate interval and may change that interval at any time. The IRB may require progress reports from the principal investigator. The IRB has the authority to suspend, terminate or require changes at any time. If the Board requires any restrictions in the protocol, e.g., a limitation on the initial number of subjects allowed before a report is provided to the IRB, this information is included in the written documentation.

4.5 Changes to an Approved Protocol

All changes to protocols must be reviewed and approved by the IRB prior to implementation. Principal investigators are required to request approval of any proposed changes in writing. The IRB requires that investigators sign a document prior to final approval stating that "The investigator agrees to report to the Committee any emergent problems, serious adverse reactions, or procedural changes that may affect the status of the investigation, and that no such changes will be made without Board approval, except where necessary to eliminate apparent immediate hazards to the subject." This statement is included in the approval notice.

The investigator must submit a cover memo with every change that outlines the addition, deletion, or revision with an assessment of the expected impact on the conduct of the study and the consent form. A statement must also be submitted that the PI certifies no other changes have been made to the protocol and the consent form. Examples of such changes are the site, the number of subjects, amendments from the sponsor, changes requested by hospitals, etc. The Chair and/or the Vice-Chair and staff review the proposed change to determine if the change is appropriate for expedited approval as defined by federal regulations. Changes not meeting the criteria will be reviewed only at an officially convened full-board meeting. In this case, the amendment is assigned to a primary reviewer who evaluates the amendment and presents a summary to the Board. All Board members receive a description of the amendment in their meeting study book. The Board discusses issues related to the amendment to include potential impact on the risk/benefit ratio of the study and takes a vote whether to approve the amendment.

A copy of the new consent form with all changes "highlighted" must be submitted and a "non-highlighted" copy of the revised consent form must also be submitted.

The IRB cannot consider changes in investigator, sites, amendments, revisions, addendums, investigator brochures, advertisements for subjects, etc. without a memo from the PI that details the impact of those items on the consent form and the conduct of the study.

It is the responsibility of the principal investigator to notify the Board of any changes to a study initially classified as exempt. At that time, the Chair will re-evaluate the exempt status of the study.

Upon final approval, the IRB office will forward to the investigator signed, stamped, and dated copies of the face page of any revisions or amendments and a signed, stamped and dated first page of the consent form.

All changes in protocol must be approved by the IRB. Implementation of any changes to a protocol without IRB approval will be considered non-compliance with these policies. To assure that investigators do request modifications, the Board will monitor all submitted documents for any suggestion of changes. An additional method of insuring that protocol modifications are requested prior to initiation will be a follow-up of any reports of such incidences from patients, board members, other investigators, etc. The IRB may require additional reports at any time during any investigation and may review the project in order to ascertain whether the rights and welfare of the subjects are appropriately protected or whether the risk/benefit ratio of the study has changed. When necessary the IRB conducts selected evaluation of investigator records to assure compliance with all federal and state regulations.

4.6 Continuing Review

IRB review of approved protocols is on-going. Approval is granted for a set period of time that is determined by the Board. This period of approval is granted for a period up to one year depending upon the nature of the study and the degree of risk to the subject. The purpose of the IRB continuing review is to assure that (a) the risk/benefit of the research remains acceptable, (b) the informed consent process and documents are still appropriate and (c) the enrollment of subjects has been appropriate. The IRB may require information from outside sources to verify that no material changes have occurred since the previous IRB review.

Studies that are considered exempt at initial review do not require continuing re-approval. However, the investigator must notify the IRB if they wish to continue the study after one year and each subsequent year from the time of initial exempt determination. Further, investigators must notify the IRB of any changes to the protocol so that an evaluation may be made to determine if the study remains exempt from IRB oversight.

As a courtesy, an application for continuation is forwarded to the principal investigator two months prior to the expiration of the currently approved period. This form must be returned prior to the deadline listed on the form. This continuation application must be completed in its entirety and accompanied by the most recently approved consent form. Incomplete or late re-approval applications may result in suspension of all activities for that protocol. Investigators cannot enroll new subjects, continue participation of currently enrolled subjects (unless medically indicated for safety), continue data collection, etc. during any period not approved by the IRB. If the investigator does not receive a signed and approved continuation of study form from the IRB before the study's expiration date, the study is administratively de-activated. Investigators must refrain from enrolling any subjects until formal notice of continuation is received. It should be noted that under all circumstances the investigator is ultimately responsible for assuring that an application for continuation and all renewal materials are supplied to the Board in a timely manner. All materials must be received in the IRB offices at the end of the month prior to the expiration date to assure review at the next meeting.

All applications for continuation of an on-going protocol are date stamped as received in the IRB office. Applications are matched to study folders and the packet is provided to the Chair for consideration.

All continuing review applications are evaluated by the Chair or designee to determine if they are eligible for expedited review and expedited re-approval. For studies receiving expedited re-approval, the continuation period will start the day the Chair approves it but in no case will that period be longer than one year. Under most circumstances, protocols that originally were given expedited review would receive expedited review by the Chair or his designee. If changes are requested in the continuation application form it must be re-evaluated to determine if the study remains eligible for approval. If not eligible for expedited review or if the status has changed, the application is forwarded to the full-board for review.

Applications that are complete and require full-board review for continuation are placed on the agenda for the full Board meeting.

If it is determined that the study must receive full-board consideration for re-approval, the Chair assigns a primary reviewer for the evaluation of the continuation of the protocol in the same manner used for new applications. A comment checklist is provided for the reviewer's summary and recommendation. The continuation application and the current consent form are provided in each Board member's study book that contains items to be considered at the full Board meeting. During the meeting, the primary reviewer presents a summary and recommendation based on the review of the full protocol file kept in the IRB office. This material is available to all members prior to and during the meeting. Members are asked for comment, a motion is made and seconded, and the Chair calls for a vote. The vote is recorded on the Chair's vote sheet. Notification of the Board's decision is made to the principal investigator following the meeting. The continuation form indicates the new approval period. That approval period starts the day of the meeting at which the application for re-approval was considered. In some cases, the application will be returned to the full Board for review. The period of approval in all cases will be for no more than one year. In some cases, the approval period will be less than one year.

The principal investigator receives a document indicating the new approval period. Any restrictions or additional requirements imposed by the Board are also communicated to the principal investigator in writing.

The IRB computer file record is updated to indicate the start day of the new period.

4.7 Adverse Event Reporting

The IRB must assess all serious adverse events (SAE) and any unanticipated problems involving risks to subjects or others associated with any protocol conducted by LSUHSC-NO employees.

An adverse event (AE) is defined as any unfavorable and unexpected sign (including abnormal laboratory findings), symptom, or disease temporally associated with the use of a medical treatment or with any procedure used in a protocol regardless of whether it is considered related to the treatment or procedure.

A serious adverse event (SAE) is defined as any adverse event that results in any of the following outcomes: death, a life-threatening situation, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or congenital anomaly/birth defect.

The IRB must assess all SAEs associated with any protocol conducted by LSUHSC employees. Key points to consider in whether to report an event are whether the event is unexpected and its severity. Keep in mind, however, that even a cough could be considered an SAE if it is unexpected and persists for many hours.

Likewise, a car accident resulting in hospitalization or in a significant disability or incapacity would be an SAE because it occurred during the conduct of a study. Such events would also occur as unanticipated problems involving risks to subjects or others and must be reported on that basis.

All SAEs and unanticipated problems must be reported promptly. In addition, an adverse event occurrence that is more severe or more frequent than described in the consent form must be reported to the IRB with a written explanation of the impact of the event on the study. All SAEs that are probably related, related, and not disclosed in the consent form must be added to the risk section of a revised consent form. A highlighted copy of the revised consent form must be included with the event report.

The reporting procedure is as follows:

- A. For subjects not enrolled by LSUHSC-NO investigators (non-local):
 1. When a safety report, manufacturer's report, MedWatch, or other information is received by an investigator that report must be assessed by the LSUHSC-NO investigator for impact on the study.
 2. The sponsor's report must be sent to the IRB accompanied by a LSUHSC-NO SAE form or reported in the LSUHSC-NO SAE tabular format for non-local SAE reporting.
 3. All SAE reports should be provided to the IRB in a timely fashion.
 4. All Data Safety Monitoring Board and similar summaries of SAE considerations must be submitted to the IRB.
- B. For subjects enrolled by LSUHSC-NO investigators special reporting requirements apply:
 1. All SAEs must be submitted in writing on the LSUHSC-NO SAE form within 5 working days. Fatal and life-threatening local events must be reported within 48 hours.
 2. All reported events are evaluated by the Chair or his designee (Initial Review) to determine if immediate action is required. Usually input from other Board members is solicited to aid in this decision. If immediate action is needed, the Chair or his designee may suspend enrollment until the SAE can be evaluated by the full Board. This may require an emergency meeting of the Board.

All SAEs occurring with subjects enrolled by LSUHSC-NO investigators will be discussed at a full Board meeting if: (a) they are considered possibly related, probably related or related to the treatment or procedure of the protocol, (b) it is an event whose frequency or severity is greater than originally expected, (c) it is a life-threatening SAE, or (d) it involves a death.

All SAEs occurring with subjects not enrolled by LSUHSC-NO investigators that result in changes to the consent form or where death occurs not due to underlying disease will also be discussed at a full Board meeting.

The Chair assigns the SAE to a primary reviewer who presents a summary to the Board. All Board members receive a description of the SAE in their meeting study book. Following a discussion of the event, the Board will determine whether the study may continue without change, if modifications are required in the protocol or consent form, if enrolled subjects should be notified, or if suspension of the study is required. If the Board votes to suspend LSUHSC-NO participation in a protocol, all appropriate parties including Institutional officials, the study sponsor, OHRP and the FDA (if applicable) will be notified.

4.8 Non-compliance by investigators

The most common lapses in investigator compliance include unreported changes in protocols, misuse or non-use of the informed consent document, and failure to submit revised protocols, modifications to a protocol, and applications for continuation of approval for studies to the IRB in a timely fashion. Problems such as these are often caused by communication difficulties. With the full cooperation of the investigator, these cases can be resolved by the IRB without jeopardizing the welfare of research subjects.

Occasionally, an investigator will either avoid or ignore an IRB request. Such cases present a more serious challenge to the IRB and to the institution. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk. When unapproved research is discovered, the IRB and the institution will act promptly to halt the research, assure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the investigator's fitness to conduct human subject research.

When the IRB learns of an issue of alleged non-compliance, the Chair will be send a Letter of Inquiry to all investigators listed as participating on the study. If the study in question is still open, the Chair will also make an immediate, initial determination if subjects are being placed at risk as a result of the alleged non-compliance. In most circumstances, the Chair will confer with other Board members before making this determination. If the Chair determines that subjects are being placed at risk, then the study will be administratively suspended and all study related activity including new accrual must be halted until completion of further investigation. If it is determined that subject safety may be compromised by termination of research activities, then intervention may continue per the approved protocol after consultation with the IRB.

The principal investigator must respond to the Letter of Inquiry within the time period specified in the Letter. The Letter will open an investigation, and based on the response from the principal investigator the matter will either be concluded and the Letter revoked or a full investigation will be conducted by the IRB. Usually a

committee of the Board will be appointed by the Chair to assist in conducting the investigation. During this investigation all investigators will be questioned by the IRB and documents related to the study will be reviewed.

At the conclusion of the investigation, the results are presented to the Board at a convened meeting of the IRB. The IRB may then conclude the investigation or, if appropriate, may terminate approval for the study and may take action against any or all of the investigators on the study. These actions may include but are not limited to warning, reprimand, censure, or suspension or prohibition from conducting further human subjects research at LSUHSC-NO. Additional action may be taken by the Institution at the discretion of the Chancellor. All actions of the Board may be appealed by first contacting the Vice Chancellor for Academic Affairs. As part of the appeal, investigators may request an appearance before the Board.

Per federal policy, any serious or continuing noncompliance with DHHS human subjects regulations or the determinations of the IRB will be promptly reported to the sponsor of the study, institutional officials, OHRP, and if applicable the FDA.

4.9 Schedule of Meetings

The IRB meets on the third Wednesday of each month. The deadline for applications to the IRB, requiring full-board consideration, is the last working Wednesday of the month prior to the next month's meeting with no exceptions. Studies eligible for expedited review will be received throughout the month and given consideration as soon as possible.

The IRB office prepares an agenda and an official notification of the time and place of the meeting under the direction of the Chair. The agenda, previous month's minutes, new applications, continuing review applications, adverse event packets, significant amendments to on-going protocols as needed for review are distributed in advance of the meeting to all members of the Board. This book also contains a listing of new and re-approved studies reviewed and approved through expedited procedures by the IRB Chair or the Chair's designee. All other approvals made by the Chair through expedited procedures, e.g., minor amendments and SAEs not requiring full-board review are presented to the Board at the full-board meeting.

4.10 IRB Records

The written procedures and guidelines of the IRB are maintained in the "LSU Health Sciences Center in New Orleans Institutional Review Board Guidebook at <http://www.lsuohsc.edu/no/Administration/rs/irb/>).

The IRB maintains an electronic and a written file for each pending and approved protocol. These files comprise the Protocol File for a study. Written documentation of activities between the investigator and the IRB are maintained in this Protocol File. All correspondence, regardless of the source, including all correspondence between the investigator and the IRB, is maintained in the Protocol File. These documents create a complete record of a protocol and its activity. Note that all

correspondence between the investigator and the FDA and/or OHRP must be copied to the IRB and will be maintained in the IRB protocol files. Protocol Files are maintained for seven years following closure of the study, at which time the files are destroyed.

Any pending study is administratively rescinded and destroyed if communications are not received from the principal investigator within a two-month period following a request for information. A new application must then be submitted if further consideration is desired of the Board.

4.11 National Cancer Institute - Central IRB (Local IRB Review Process)

Louisiana State University Health Sciences Center – New Orleans (LSUHSC–NO) and the National Cancer Institute (NCI) have initiated an authorization agreement whereby the LSUHSC–NO IRB will defer to the Adult and Pediatric CIRBs on certain CIRB-approved national multi-center cancer treatment trials.

Studies reviewed by the Adult CIRB include all Phase III Adult Cooperative Group treatment trials approved by CTEP (ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC, NSABP, RTOG and SWOG). The Adult CIRB may review other CTEP-approved Phase III clinical trials that are approved by CTEP, even if the sponsor is not a Cooperative Group. The Board may also review Phase II studies for rare tumors that appear on the CTSU menu.

Studies reviewed by the Pediatric (Ped) CIRB include all Pilot, Phase II, and Phase III Children’s Oncology Group (COG) treatment trials approved by CTEP and/or DCPC. The Ped CIRB may review other trials approved by DCPC, and also other federally-funded trials (i.e., via R01 grants). The Board may review other CTEP-approved clinical trials as directed by CTEP, even if the sponsor is not a Cooperative Group.

The CIRBs will conduct initial and continuing review of studies, as well as any changes to the protocol, and will review all non-local serious adverse events. The LSUHSC–NO IRB will address local context issues, review local serious adverse events and protocol deviations, and monitor conduct of the study at the local site(s).

The LSUHSC–NO IRB will conduct a “facilitated review” of a CIRB-approved protocol in order to determine whether to accept the CIRB approval, whereby the CIRB would become the IRB of record for that protocol. If the determination is made not to accept the CIRB approval; e.g., if more changes are required than are acceptable to the CIRB, then the protocol may be reviewed under full board procedures by the LSUHSC–NO IRB.

A. Facilitated Review Process

The LSUHSC-NO IRB will perform facilitated reviews of CIRB-approved protocols as follows:

1. The principal investigator who wishes to enroll subjects in a CIRB-approved protocol will download the Local IRB Facilitated Review Packet, and any other documents as desired by the LSUHSC-NO IRB, from the Participant side of the CIRB website www.ncicirb.org and submit these documents to the LSUHSC-NO IRB.
2. The LSUHSC-NO IRB coordinator for CIRB protocols will make a preliminary review of the submitted materials to ensure that the packet is complete and that the ICF is in the proper LSUHSC-NO format with all required local language inserted.
3. At least one voting member of the LSUHSC-NO IRB in conjunction with the LSUHSC-NO IRB Chair will conduct the facilitated review of the study. The reviewer and Chair will determine whether to accept the CIRB review and whether there are local concerns which need to be addressed. The reviewer and Chair examine the materials submitted from the principal investigator, and any additional information as deemed appropriate, in order to decide whether a particular protocol and ICF are acceptable and whether they are appropriate in their local context. The LSUHSC-NO IRB has the option to accept the CIRB approval "as is", accept it with *de minimus* modifications, or decide not to accept the CIRB review. In this case, should the investigator want to open the study, s/he will be required to submit the protocol for local, full board review. The reviewer and Chair are authorized by the LSUHSC-NO IRB to make determinations regarding acceptability of the protocol as approved by the CIRB along with any changes which may be deemed necessary to the ICF.
4. The LSUHSC-NO IRB may add local language to the ICF dealing with state and local law, institutional requirements, or IRB policies. No CIRB-approved information may be deleted from the ICF. The LSUHSC-NO IRB may also make minor word substitutions or additions to the ICF, particularly to facilitate better comprehension by the local population, as long as the proposed changes do not alter the meaning of the CIRB-approved contents. Additional risks may be added to the ICF. The reviewer will communicate with the investigator regarding any changes necessary prior to acceptance; the investigator will re-submit any such revisions to the LSUHSC-NO IRB. Revisions/changes to the local ICF other than those described above require full board review at the local level. Facilitated review may not be used, and the CIRB cannot serve as the IRB of record for that protocol at LSUHSC-NO.
5. The LSUHSC-NO IRB will notify the Central IRB Operations Office of its acceptance of the CIRB review of a protocol. The coordinator will accomplish this by clicking on the "Facilitated Review Acceptance"

button/link within the main menu for each protocol and completing the Facilitated Review Acceptance Form. This form must be completed and submitted for the CIRB to become the Official IRB of Record for a particular study. A separate form will be submitted for each protocol review that is accepted.

6. The LSUHSC–NO IRB will notify the principal investigator of its determination with regard to each protocol submitted.

B. Further Review Procedures

The LSUHSC-NO IRB will perform reviews of further documentation as follows:

1. For all protocols for which the CIRB is the IRB of record, the principal investigator will download any amendments to the CIRB-approved protocol, along with the CIRB approval documentation, and submit them to the LSUHSC–NO IRB for review. The principal investigator will apprise the LSUHSC–NO IRB of continuing review approval of the protocol by the CIRB and will submit the CIRB Continuing Review approval documentation and any revisions to the ICF. The CIRB renewal date becomes the re-approval date of record. The voting member/s retain/s the option not to accept the CIRB review and can choose to request a local full board review, in which case CIRB would no longer be the IRB of record for that protocol. The LSUHSC-NO IRB would then submit a closure form to the CIRB and open the protocol locally under the jurisdiction of the LSUHSC-NO IRB.
2. The LSUHSC–NO IRB will review all local SAEs generated during the conduct of the study, as well as any protocol deviations/violations. Any actions taken as a result of problems identified in these areas will be shared with the CIRB and reported as required by the procedures established by the study’s lead organization.

C. Further Responsibilities of the LSUHSC–NO IRB

The LSUHSC-NO IRB will:

1. Maintain a Federal Wide Assurance (FWA) and designate the NCI CIRBs under the FWA
2. Maintain a human subjects protection program, as required by the DHHS OHRP
3. Maintain a local IRB whose membership satisfies the requirements of 45 CFR 46 and 21 CFR 56
4. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects
5. Ensure that local IRB members and local investigators receive proper initial and continuing education on the requirements related to human subjects protections

6. Notify the CIRB immediately if there is ever a suspension or restriction of the local IRB's authorization to review studies
7. Perform oversight of the local conduct of the study, monitoring study compliance, thereby ensuring the safe and appropriate performance of the research at its institution. There will also be the provision of a mechanism by which complaints about the research can be made by local study participants or others
8. Notify the CIRB immediately if there is a suspension or restriction of a local investigator
9. Provide to the CIRB and keep current the names and addresses of local contact persons who have authority to communicate for the local IRB, such as the local IRB administrator.
10. Notify the CIRB if there is ever a change in the acceptance/rejection of the CIRB review for any given protocol
11. Maintain in the local IRB records documentation of the decision reached for each protocol, and evidence that it has received and considered all CIRB material relevant to the study

5.0 ITEMS OF SPECIAL INTEREST

5.1 Emergency Use Notification and Reporting Procedures

Emergency use exemption is allowed under 21 CFR [56.104c]. All LSUHSC-NO employees must report any usage allowed under 21 CFR [56.104c]. This report must be received in writing by the LSUHSC IRB within five working days. This exemption allows for one (1) emergency use of a test article by the institution (LSUHSC-NO) without prospective IRB review. The IRB requires that any subsequent use of the investigational product by any LSUHSC-NO employee must have prospective IRB review and approval. For additional information see the FDA Information Sheet "Emergency Use of an Investigational Drug or Biologic (see Appendix for Selected FDA Information Sheets).

LSUHSC-NO does not participate in exception from informed consent for planned emergency research as noted in 21 CFR 50.24.

5.2 Assessment of Risks to Subjects

No subject in a scientific investigation can be exposed to unreasonable risks to health or well-being. An individual is at risk if exposed to the possibility of any harm (e.g. physical, psychological, sociological, or legal). Determination of risk is a matter of the application of common sense and sound professional judgment. The LSUHSC-NO IRB is the final authority at this institution.

- A. "No risk" refers to investigations in which the subject is not placed in jeopardy of any kind. Examples are use of educational tests, observation of public behavior or interview procedures, each under certain conditions. This type of investigation may qualify for exempted verification by the IRB.
- B. "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering the probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples are voice recordings made for research purposes, moderate exercise by healthy volunteers, veni-puncture under certain conditions, or collection of urine specimens. Some "minimal risk" protocols may qualify as involving "vulnerable populations."
- C. Psychological injury might involve subjection of subjects to deceit or withholding of information, public exposure, humiliation, invasion of privacy, or coercion. Social injury can occur if there is risk of loss of personal reputation or professional status, defamation of character, personal degradation in the eyes of others, or revelation of information related to sensitive social issues.

Examples of projects which may involve "greater than minimal risk" are surgical procedures, including removal of organs or tissues for biopsy, transplantation, or banking; administration of drugs, chemicals, biological agents, or radiation; use of indwelling catheters or electrodes; or the requirement of strenuous physical exertion. All projects involving greater than minimal risk and/or vulnerable populations must be reviewed at a regularly scheduled meeting of the IRB.

5.3 Use of Radioactive Isotopes

If radioactive isotopes are used in vivo, a radioisotope approval must be submitted to the IRB. Call The Office of Radiation Safety (568-6585) for further information and an application form (see the LSUHSC-NO website at <http://www.is.lsuhscc.edu/safety/radiation.aspx>). Radiation Safety approval should be submitted to the IRB. This approval must be received prior to IRB approval.

5.4 Subject Entry Site Approval

Since most institutions have committees that assess the impact of the proposed research at their facility, it is the responsibility of the investigator to assure that approval has been obtained from the appropriate officials of the sites listed on the application form.

5.5 Waiver of Informed Consent and Waiver of Documentation

A. Waiver of Informed Consent

Federal regulations at 45 CFR 46.116(d) allow for waiver of informed consent when the following conditions are met:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The issue of the test of practicability can be met, for example, by:

1. The need of a large numbers of subjects
2. A presumed or demonstrated inability to contact subjects for whom contact information may not be accurate
3. The fact that many of the subjects may have died
4. The fact that a lack of data from a few subjects may make the number of subjects available for the study too few to make the study valid

To request a waiver of informed consent, each of the above listed four questions must be addressed in the request.

B. Waiver of Documentation of Informed Consent

Federal regulations at 45 CFR 46.11.c allow for a waiver of documentation of informed consent if:

1. 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
2. The research presents no more than minimum risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

For studies regulated by the FDA, regulations at 21 CFR 56.109.c also allow for a waiver of documentation of informed consent if the research presents no more than minimum risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

5.6 Subject Population

It is the responsibility of the principal investigator to identify the sources of potential subjects; describe the characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health; identify the criteria for inclusion and exclusion; explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized individuals (mentally disabled, prisoners or others) especially those whose ability to give voluntary informed consent may be in question. In addition, the rationale for involvement of disproportionate numbers of racial or ethnic minorities, the aged, or persons of low socioeconomic status must be stated.

Subjects from VULNERABLE POPULATIONS are those whose ability to give voluntary informed consent may be in question. Examples of vulnerable populations are children, pregnant women, fetuses, terminally ill patients, prisoners, institutionalized persons (mentally ill), wards, and individuals who might be under psychological pressure to volunteer. If vulnerable populations are to be used, investigators must deal thoroughly with the potential for risk. It should be understood that the definition of "minimal risks" for vulnerable populations is different than for non-vulnerable populations. Consultation with the IRB Office on this issue is strongly urged if vulnerable populations are being asked to participate as research subjects. Federal regulations require additional IRB considerations if vulnerable populations of subjects are used.

Under most circumstances, employees/students at LSUHSC-NO may not participate in projects where the investigators, in their roles of faculty members or supervisors, are involved in grading the academic or clinical performance or otherwise evaluating the subjects. Research involving students/employees as subjects is reviewed on a

case-by-case basis. The single most important factor in considering exceptions to the above rule is the complete absence of either coercion or the perception of coercion by the students/employees who are asked to participate. Other factors affecting this decision of exception include: having a mechanism to assure anonymity; having a method to assure that no penalties can be imposed on students/employees who refuse to participate, etc. It is unusual for the IRB to approve projects utilizing students/employees that do not fit in either the exempted or expedited categories. The request to include LSUHSC-NO students/employees must be included in the application project summary.

5.7 Subject Payment

Compensation to subjects must never constitute an undue influence or coercion to participate, and should be limited to nominal payment for time and inconvenience of participation and or travel expenses. Such compensation should not be construed nor described as a benefit of the research. Any payment(s) made must be *pro rated*, based on the time actually spent in the study, regardless of whether or not the subject completes the study. Payments must be made in equal amounts at each visit during the course of the study.

5.8 Advertisements for Subjects

If notices are posted or other advertising used for recruitment of volunteers to participate in the research, the specific advertisement and methods of recruitment must be approved by the IRB prior to use. Any type of advertising for research subjects that is intended to be seen or heard by prospective subjects is considered to part of the informed consent and subject selection process. Since this may be the initial contact by the investigator with the subject, the IRB must ensure that the information is not misleading to subjects. This is especially important when a study may involve subjects who are likely to be vulnerable to undue influence, for example, financially impaired subjects.

When advertising is to be used, the IRB must review both the information contained in the advertisement and the mode of its communication. This is to determine that the procedure for recruiting subjects is not coercive and that the recruitment material does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

Advertising for recruitment of participation in investigational drug, biologic or device studies should not use terms such as "new treatment" or "new medication" without explaining that the test article is investigational.

A phrase such as "you will receive new treatments" incorrectly implies that all study subjects will be receiving newly approved products of proven worth. Advertisements should not promise "free medical treatment", when the intent is only to say subjects will not be charged for taking part in the investigation.

If an investigator decides to begin advertising for subjects after the study has received IRB approval, the advertising is considered as an amendment to the ongoing study and must be reviewed by the IRB. When such advertisements are easily compared to the consent, the IRB will review and approve the advertisement using expedited procedures. When the comparison is not obvious or other complicating issues are involved, the advertisement will be reviewed at a convened meeting.

Generally, advertisements should be limited to the information the prospective subjects need to determine their eligibility and interest. The following items must be addressed to qualify the advertisement for review:

1. The name of the investigator, the name and phone number of the contact person for the study and the name of the institution (e.g. LSU Health Sciences Center in New Orleans)
2. The purpose of the research (e.g. the condition under study or the goal of the project)
3. The eligibility criteria (which may be in summary form, or listed as bullets or points)
4. The time frame required for participation
5. A short list of benefits (Note that payments to subjects for participation are not benefits. The payment may be mentioned however it cannot be emphasized.)

Investigators who require assistance with advertisement formatting or composition should contact the LSUHSC-NO Director of Information Services at Ph.# 568-4806. This office must be contacted if the recruitment material will appear in the print media or will be presented on television or radio.

5.9 Educational Materials for Subjects

Education materials related to the consent process or to be used as part of the study, e.g. videos, brochures, etc. must be reviewed and approved by the IRB before use. If available at the time, these items must be submitted with any new application for IRB approval.

5.10 Confidentiality of Data and HIPAA Privacy Rule

When the research involves collection of data which might be harmful to subjects if disclosed to third parties in an individually identifiable form, the investigator must be attentive to the adequacy of provisions to protect the confidentiality of data. The investigator must limit the collection of personal information to that which is essential for the research. Depending upon the degree of sensitivity of the data, the methods for protecting the confidentiality of data may include coding or removal of identifiers as soon as possible, limitation of access to data to the investigator and authorized staff, the use of locked file cabinets, and plans for the ultimate disposition of data. The investigator should be aware of the extensive vulnerability

of research data to subpoena, particularly in studies that collect data that would put subjects in legal jeopardy if disclosed. The subject names should be recorded only when necessary and they must be informed that their identity can be protected only to the extent allowed by law.

All studies must adhere to regulations concerning privacy at 45 CFR Parts 160 and 164 (Standards for Privacy of Individually Identifiable Health Information or **HIPAA Privacy Rule**). Investigators are directed to the LSUHSC-NO web site “HIPAA and Research” at <http://www.lsuohsc.edu/no/Administration/rs/hippa/> for additional information related to these regulations.

5.11 Record Keeping by Investigators

Copies of all signed consent forms and associated HIPAA Authorization documents must be kept by the principal investigator and made accessible for review by the IRB. Files of all signed consent forms and associated HIPAA Authorization documents from research must be retained for a period of seven years after the date of the subject’s signature or when the subject’s participation in the study has ended.

For FDA regulated studies, Case Report Forms and other related study documents must be retained for two years following the termination or discontinuation of the investigational study (not merely an investigator’s portion of a study) occurs or the records are no longer required to pursue marketing approval from the FDA.

Projects involving the intraocular lens have the following additional requirements: Files must be maintained A.) A period of two years after the date on which the Food and Drug Administration approves the marketing of the intraocular lens for the purposes that were the subject of the study. B.) A period of five years after the date on which the results of the study are submitted to the Food and Drug Administration in support of the marketing of the intraocular lens for the purpose that was the subject of the study.

5.12 Human Subject Protection Educational Policies and Resources

A. Investigator(s)

It is the policy of the LSUHSC-NO IRB that all LSUHSC-NO investigators desiring to engage in research using human subjects must familiarize themselves with all IRB policies and procedures and related federal regulations. Investigators new to the Institution must meet with the IRB Chair, Vice-Chair or a staff member prior to submission of an IRB application. Investigators should maintain an on-going relationship with the IRB office staff to gain assistance in the preparation of applications and to gain assistance in following all IRB policies and procedures during the conduct of their studies. This will help assure that both investigators and the Institution remain in compliance with all state and federal regulations regarding research involving human subjects.

All employees involved in human subjects research must take advantage of the educational opportunities listed below.

- All investigators and their research team members submitting an initial or continuation application to the IRB must read the LSUHSC IRB “[Guide](#)” and the “[Belmont Report](#)”.
- In addition, they must complete appropriate (Biomedical or Social/Behavioral learner groups) Collaborative Institutional Training Initiative (CITI) <http://www.lsuhscc.edu/no/administration/rs/irb/default.htm> modules as described in the Instructions for completing CITI training at <http://www.lsuhscc.edu/no/administration/rs/irb/CITI%20Instructions.pdf>
- In addition to training in human subjects’ protection, any investigative team conducting FDA regulated research must complete the appropriate learner group for Good Clinical Practice (GCP) also available at <http://www.lsuhscc.edu/no/administration/rs/irb/default.htm> .
- Continuing education of all investigators and their team members is required every three years. Appropriate learner groups in CITI are available for this purpose.

B. Members

Members of the IRB have the important responsibility of protecting the many individuals of our community that volunteer to participate in this Institution's human subjects research programs. New Board members are expected to familiarize themselves completely with the IRB process in the manner described above for investigators. New members are asked to attend a number of scheduled IRB meetings to observe and to contribute to the discussion at the meeting before being assigned primary reviewer responsibility. New members should interact with the IRB Chair, Vice-Chair and IRB office staff about the requirements of and assistance with reviews.

For the purposes of continuing education, at each IRB meeting an “Educational Component” is included where issues of current interest related to human subject protection are discussed. Related written materials are distributed as part of the “Educational Component” and a copy of the Human Research Report is given to each member at each meeting. Additional items of interest are distributed by email between.

All members are required to read the LSUHSC-NO “Guidebook”, the “Belmont Report” and to complete the “IRB Members” learner group modules in the CITI program <http://www.lsuhscc.edu/no/administration/rs/irb/default.htm> .

C. IRB Staff

All IRB staff are required to read the LSUHSC-NO IRB “Guidebook”, the “OHRP Guidebook”, the “Belmont Report” and to complete all CITI learner modules at <http://www.lsuhscc.edu/no/administration/rs/irb/default.htm> . They are carefully trained to understand all federal regulations related to human subjects protection

and drug and device development. Continuing education occurs during attendance at all IRB meetings, by participating in the IRB Forum list server, by attending regional and national IRB conferences and workshops and completing continuing education modules offered by CITI.

D. Other Educational Opportunities

1. Lectures

Presentations by the IRB Chair, Vice-Chair and staff concerning IRB issues are made at departmental faculty meetings, business manager meetings, workshops, courses and other academic settings to familiarize investigators and staff with the IRB process, human subject protection, and with IRB policies and procedures open to all on campus. In addition, a number of IRB members lecture on IRB issues in ethics classes taught on campus.

2. Educational Meetings

On an unscheduled basis, the Institution sponsors, with other institutions and national organizations like OHRP, locally held meetings concerning IRB issues and human subject protection and invites consultants to present such issues to our employees. OHRP, PRIM&R, NCURA and AAMC have numerous national and regional meetings dealing with IRB issues and announcements of these meetings are widely distributed. Our investigators and IRB members are encouraged to attend such meetings. The IRB Chair, Vice-Chairs and staff regularly attend such meetings.

3. Resources

Educational materials mentioned below are available from the IRB office to assist all investigators in familiarizing themselves with the history of human subjects protection, factors necessitating the development of the IRB process and regulations underlying IRB policies and procedures. Materials are also available in LSUHSC-NO libraries. The IRB library, housed in the IRB office, contains numerous videos and written materials on the history and operation of IRBs and human subject's protection. This includes Cynthia Dunn and Gary Chadwick's book titled *Protecting Study Volunteers in Research* (Center Watch, Inc. Boston, MA 1999). Copies may also be purchased in the LSUHSC-NO campus bookstore. OHRP, FDA and other organizations and institutions have educational materials concerning human subject protection and IRB function. Electronic communications of such information are also widely distributed.

5.13 Child Assent Policy

Assent is a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. In any research project in which children are used as subjects, adequate provisions for soliciting assent must be described in the IRB application and included on the consent form. Assent should be obtained unless it is determined by the investigator that the child is not capable of providing assent. In most circumstances, assent should be obtained of any child over seven years of age. However, in making this determination, the child’s age, maturity, and psychological state must be taken into consideration. If assent is not obtained when requested by the IRB, then the reasons for not obtaining assent must be fully documented. This documentation must be particularly thorough in the case of research that is non-therapeutic in nature and/or does not hold out the prospect of direct benefit for the child. The IRB may determine that as a group the children asked to participate in a research project are incapable of providing assent. If the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the IRB may determine that the assent of the children is not a necessary condition of proceeding with the research.

5.14 Protocol Deviations

All protocol deviations must be reported to the IRB.

5.15 Notification of Termination of the Study

Termination of a research protocol must be reported in writing by the principal investigator to the IRB. The report must provide the number of subjects enrolled, the number withdrawn and any results that are known at the time of closure.

5.16 Institutional Bio-safety Committee Review

All research projects conducted at LUSHSC-NO must receive Institutional Bio-safety Committee (IBC) approval. The IBC application is available at http://www.lsuohsc.edu/no/administration/rs/IBC_Protocol_Submittal_Form.doc

IBC approval must be provided to the IRB office before IRB approval will be granted.

5.17 Quality Assurance/Improvement Studies

While QA/QI studies do not require IRB approval or oversight, making the determination whether a project is QA/QI or research can often be difficult. It must be kept in mind that projects can be both QA/QI and research requiring IRB approval and oversight. Therefore, a determination of this QA/QI status must be requested from the LSUHSC-NO IRB before any QA/QI project to be conducted by LSUHSC-NO personnel is initiated. Note that this requirement does not apply to QA/QI projects conducted by LSUHSC-NO employees for HCSD or other hospital operations.

6.0 The IRB Application

A. General Information

Research involving the use of human subjects must be approved by the department head and then by the IRB prior to implementation. In addition to protocols requiring full board approval, certain categories of research may qualify for expedited or exempt review. This means they may be reviewed and approved by the IRB Chairperson.

All incomplete or inadequate IRB application packets will be returned to the respective department heads without review. As a result, applications that are returned will experience an additional delay of one month over and above the current schedule.

The IRB application consists of the application form, the project summary, the consent form, the expanded protocol and any other related materials such as the Investigator Brochure or assessment tools. The FORMS Section contains both an IRB application and instructions for completion of the consent form. An expanded explanation of the information provided below is given in the Instructions for the Application Form and should be carefully reviewed prior to completing an application. Additional forms for submitting protocols to the IRB may be obtained from the Institutional Review Board, located at 433 Bolivar Street, Room 206, in the Resource Center (Ph. # 568-4060). Completed forms for IRB review must be submitted to the above address. Meetings are scheduled on the third Wednesday of each month. To be reviewed, protocols must be received by the last Wednesday day of the month preceding the meeting.

B. Application Form

All sections of the form must be completed prior to submission to the IRB Office.

Project Summary (Expanded information regarding this portion of the application is included in the IRB application instructions.)

The project summary, number 14 of the application form, should be a clear explanation of the aims and specific objectives of the study and the procedures that will be followed. Since some IRB members are lay members representing the community, avoid using highly technical language and provide explanations in lay terms. Describe the study design, particularly in terms of selection of study groups (double-blind random) and procedures for each study group, if these differ (e.g., controls versus patient groups). Also include previous experience, risk to subjects, safeguards, alternatives, and anticipated information to be gained from the study.

C. Informed Consent

1. Informed consent is an individual's voluntary agreement to become a subject of research after having been informed of the purpose of the study, the procedures that are experimental, and potential risks or benefits to reasonably be expected. Additional information that must be given to the subject includes expected duration of subject's participation, selection of subjects, alternative treatment procedures available, extent of record confidentiality, and all financial issues.
2. The investigator should answer any questions, and further, be satisfied that the subject, or his legally authorized representative, understands the procedure or treatment the subject is to undergo. To this end, the explanation must be in the language and vernacular the subject best understands. It is neither practical nor possible for complete understanding to be achieved; thus, an extra burden is placed on the investigator to serve the best interests of the subject. A legally effective consent form is to be read to or by the subject and must also be signed by the subject or his/her legally authorized representative. Consent Forms in languages other than English are sometimes required. These must be submitted for IRB review and must be accompanied by certification (e.g. legal notary or translation company) that the form is an accurate translation of the English version. If a subject does not understand English, then it is mandatory that a copy of the informed consent document in the language the potential subject understands be provided to the individual.
3. Consent procedures for research involving children must be carried out in accordance with applicable federal regulations, and special provisions should be followed in obtaining parental permission and the child's assent. The investigator is responsible for following these regulations.
4. In giving consent, the subject should show the ability to exercise free power of choice without intervention of any element of constraint or coercion. The agreement should include no exculpatory language through which the subject is made to waive, or appear to waive, any legal rights, or to release the investigator and institution from liability for negligence. The investigator must honor a request by any subject to withdraw consent and to discontinue participation in the investigation and do so without prejudice. Should significant findings develop during the course of the research that may relate to the subject's willingness to continue participation that information must be provided to the subject.

5. Investigators are responsible for retaining signed consent forms in their personal research files. In addition, the principal investigator should permanently keep copies of the signed consent forms in the subject's hospital/clinic chart as a matter of record. Because consent form documents are an agreement between two parties, the subject must be given a copy to keep. Instructions for completion of consent forms are attached to the IRB application form. The principal investigator must tailor each point individually to the specific study.
6. LSUHSC-NO does not participate in exception from informed consent for planned emergency research as noted in 21 CFR 50.24 .

D. Expanded Protocol

Two copies of an expanded protocol must be submitted along with the application and consent form. For drug studies, this usually consists of the company-prepared protocol. For all other studies, a separately prepared expanded description of the study must be provided.

This document may include but is not limited to the following: introduction, background, rationale for conducting the study, objectives, study design, duration, number of subjects, selection of subjects, study methods and statistical considerations.

E. Grant Applications

For all IRB applications related to a federal grant proposal a complete copy of the full grant proposal must be provided for review by the IRB.