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LOUISIANA STATE UNIVERSITY AND AGRICULTURAL
AND MECHANICAL COLLEGE (LSU and A&M College)

LSU INSTITUTIONAL REVIEW BOARD

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Policies and Procedures

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This guide will be updated as required. The on-line copy maintained on the IRB Web site is the authoritative edition and will bear the latest date edited.

Other pertinent documents are also available at this location or from the IRB office:
<http://www.lsu.edu/research>

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LSU IRB POLICIES and PROCEDURES

1.0 Summary

The primary goal of the IRB is to ensure the safety and welfare of human subjects in research and scholarly projects.

The Institutional Review Board (IRB) is responsible for ensuring compliance with the exacting federal requirements that govern ALL research with human subjects (whether funded externally, or not), unless they meet specific criteria for exemption.

It is the IRB's goal to assist faculty to conduct successful studies with human subjects, by helping them meet the criteria for IRB approval. The IRB also seeks to limit liability for LSU as a by-product of protecting subjects.

All projects must be submitted to the IRB Office for approval or exemption using standard forms and guidelines available on request. In no event may a project with human subjects begin before written exemption, or written IRB approval is received.

Non-exempt projects must be reviewed and approved at a convened meeting of the IRB, except for certain minimal risk projects that qualify for an expedited review performed by one or more IRB members.

Major protocol changes of existing protocols approved at full review also require full review.

Projects must be re-reviewed by the IRB no more than 365 days after approval (at a full IRB meeting if the original approval required full IRB review), even if the start date of the research is postponed. The IRB office will issue requests for a progress report in advance of the review date; continued approval will be contingent on an adequate response.

All inquiries for the IRB should be directed to Dr. Alex Cohen, Chair at (225) 578-8692, 130 David Boyd Hall, LSU.

2.0 Introduction

As mandated by federal law, the Louisiana State University and A&M College in Baton Rouge (LSU) has established an Institutional Review Board to review, and exercise oversight over proposals to use human subjects in research conducted under the sponsorship of, or in any other way associated with the University.

This guide sets forth LSU's policies and procedures to comply with the various federal requirements and otherwise to protect the interests of the various parties.

3.0 Statement of Principles

The principles upon which the regulations governing human research are founded are embodied in the Belmont Report. LSU regards these principles as the foundation for its program to protect the welfare of human subjects in research.

4.0 Purpose of IRB

The primary purpose of the IRB is to protect the interests of human research subjects and ensure that physical, psychological and social risks to them are minimized, and when present, justified by the importance of the research and agreed to by the subjects.

Secondarily, the IRB seeks to protect the university and the investigator(s) from possible adverse consequences of research with human subjects.

The IRB seeks to assist the investigator to design his/her research and projects so that they are in compliance with federal and university requirements, so that they can be approved and conducted.

5.0 Scope

ALL LSU systematically planned research/projects using living humans as subjects, samples, or data obtained from living subjects, directly or indirectly, with or without their consent, must be approved in advance by the LSU Institutional Review Board, unless they meet the criteria for exemption from IRB oversight and are formally exempted. LSU projects include projects in which LSU personnel and students participate, whether conducted on campus or elsewhere, and projects that use LSU funds or facilities even if not conducted by LSU personnel. Review and approval by another IRB does not negate the requirement for review and approval by the LSU IRB (if another IRB shares jurisdiction over a project, the LSU IRB requires a copy of that IRB's determination).

The LSU IRB reviews all non-exempt projects that use human subjects as objects of discovery, and does not limit its activities to the narrow definition of research used by DHHS in 45 CFR 46.

6.0 Exempt Projects

Formal instructional activities are not included under this policy and recipients of instruction are not regarded as human subjects for the purposes of this document, unless the students are also used as an object of some secondary research or quasi-research activity.

Interview with persons for the purpose of journalism is not covered by this policy. With these exceptions, the only projects that may be exempted from IRB approval are those defined in 45 CFR 46; an APPLICATION FOR EXEMPTION FROM INSTITUTIONAL OVERSIGHT is available on request or on the IRB web site. This document does not further consider exempt projects.

7.0 Authority

The Department of Health and Human Services (DHHS) regulations that define the authority of the IRB are found in 45 Code of Federal Regulations 46. Additional requirements are imposed by the Food and Drug Administration when Investigational New Drugs and Medical Devices are used in research. In addition, LSU has filed an Assurance with DHHS describing the standards and procedures to which the University will adhere in overseeing research with human subjects. It is intended that the policies and

procedures in this Guide be consistent with the referenced documents.

8.0 Responsibilities

8.1 University/Institutional Official

The Institutional Official is the University point of contact with DHHS' Office for Human Research Protections (OHRP), and he bears ultimate responsibility for ensuring University compliance with the federal requirements. At LSU, the Institutional Official is the Associate Vice President for Research (225) 578-5833.

The Institutional Official appoints the IRB members.

The institution is required to vest in the IRB those powers required by 45 CFR 46, and may not overrule decisions of the IRB regarding project disapproval, or conditions for approval. However, IRB approvals may be overruled by the University.

The IRB may disapprove, discontinue, suspend or limit approved activities at any time it is deemed in the interest of protecting the rights and welfare of human subjects. Funds for studies may be withheld at the discretion of the University administration.

The Institution must provide resources to the IRB sufficient for it to carry out its duties.

The Institution will notify OHRP of serious or continuing non-compliance with the terms of its Assurance or 45 CFR 46.

8.2 Chair, IRB

The Institutional Official has delegated to the Chair of the IRB, the responsibility to manage a procedure to determine which projects using human subjects require IRB review and approval, and which may be exempted under the terms of 45 CFR 46. The Chair refers to the IRB all studies which do not meet the criteria for exemption.

The Director of Sponsored Projects is responsible for examining all grant applications to determine if necessary IRB review has been instituted.

8.3 IRB Chair

Staffing and support for the IRB is maintained in the Office the IRB Chair. The Chair may appoint a co-chair or a member to act in his absence.

The IRB chair will be responsible for:

- (a) Maintaining records as provided in 45 CFR 46
- (b) Convening IRB Meetings and developing the agenda
- (c) Preparing minutes
- (d) Issuing formal decisions on applications
- (e) Informing the Institutional Officer with written documentation of serious and continuing non-compliance problems within 2 weeks of his discovery
- (f) Informing the University community on new requirements and areas of concern regarding human subjects
- (g) Advising investigators on requirements regarding research with human subjects
- (h) Ensuring all necessary information on research with human subjects is widely available
- (i) Developing policies and procedures to implement the federal regulations and Assurance

8.4 IRB Members

Voting members are appointed by the Institutional Official and are listed in the IRB Assurance with OHRP. Named alternate members may vote if the person to whom they are an alternate is absent or cannot vote by reason of conflict of interest.

IRB members are responsible for:

- (a) Ensuring projects are in compliance with 45 CFR 46 and the terms of LSU's Assurance with OHRP
- (b) Reviewing project proposals and evaluating them in terms of the criteria for approval (45 CFR 46), as well as in any other terms that appear relevant
- (c) Sending project evaluations to the IRB office in advance of a convened meeting whenever possible
- (d) Attending IRB meetings at a reasonable frequency, and entering into a process of discovery and discussion concerning the issues inherent in each proposal
- (e) Making recommendations for reducing risk and improving the informed consent process, and otherwise to improve human protection
- (f) Recommending improvements in policies and procedure to improve the integrity and adequacy of human protection
- (g) Voting to approve or disapprove protocols, or recommending modification in protocols to enable approval
- (h) Informing the Chair of noncompliance problems of which they become aware

8.5 Investigators

Research investigators who intend to involve human research subjects and who believe their studies qualify for exemption from IRB oversight under the terms of 45 CFR 46 must apply for exemption through the procedure established by the IRB Chair.

Responsibilities of the investigator include those specified in the Assurance with OHRP:

Research investigators must acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance.

Research investigators are responsible for providing a copy of the IRB-approved informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained by the investigator for at least 3 years after the end of the study.

Research investigators will promptly report proposed changes in previously approved human subject research activities to the IRB. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

Research investigators are responsible for reporting progress of approved research to the IRB as often as and in the manner prescribed by the approving IRB on the basis of risks to subjects.

Research investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to subjects and others.

No research investigator who is obligated by the provisions of this Assurance, any associated Inter-Institutional Amendment, or Noninstitutional Investigator Agreement, will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see Section 116[f]). However, such activities will not be counted as research nor the data used in support of research.

Research investigators will advise the IRB Chair, and the appropriate officials of other institutions of the intent to admit human subjects who are involved in research protocols for which this Assurance or any related Inter-Institutional Amendment or Noninstitutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OHRP-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

In addition, investigators must:

- (a) Be directly responsible for the safety (physical and psychological) of each subject
- (b) Treat subjects with respect as autonomous individuals
- (c) Comply with 45 CFR 46, LSU's Federalwide Assurance (FWA) with OHRP, and any stipulations of the IRB
- (d) Be familiar with the Belmont Report and this Policy and adhere to these principles
- (e) Adhere to the approved protocol and consent process
- (f) Obtain approval for any changes in advance (except in an unusual circumstance where it is necessary to deviate from the protocol to protect the well-being of a subject)
- (g) Report all deviations, non-compliance and adverse events promptly to the IRB; and
- (h) Ensure that all colleagues and persons working under his/her direction meet the same standards.
- (i) Protect all electronic and other data in accord with LSU's security of data policy (PS06.20)

Projects under the jurisdiction of the IRB must be directed by an LSU employee. The IRB may, at its discretion, make exceptions to this policy, for instance in the case of unpaid adjunct appointees, or in instances where projects originating externally use LSU resources, but LSU employees do not help to direct the project. Students must arrange for a LSU employee (usually their major professor or

instructor) to act as project director or principal investigator and take full responsibility for the project and welfare of the subjects.

9.0 Project Review

9.1 Recusal

An IRB member who has a conflict of interest as investigator on a project, or a financial interest in it, is required to declare the conflict. In this circumstance the individual may not take an active part in proposal review, except to provide requested information, and will absent himself from the final Board discussion and vote.

9.2 General review procedures

Proposals will be reviewed in terms of the criteria which the IRB is required by 45 CFR 46 to consider: these are incorporated into questions in the IRB application.

Reviewers will indicate whether or not the project appears to present more than minimal risk.

9.3 Expedited Review

(1) Any IRB member may receive an application for expedited review, and on determining the application is complete, determine whether it meets the criteria for expedited review, and if so whether it is advisable to perform expedited review. He/she may perform such review or refer it to a member more experienced in the field. If the project creates more than minimal risk, it may not be considered by expedited review.

(2) Special consideration will be given to full review when members of vulnerable groups are in the study population.

(3) If a decision is made to approve, the application and the checklist will be sent to the Chair who will issue the formal approval to the applicant. If a project cannot be approved by expedited review, then it must be referred to a full IRB review.

(4) A list of projects approved by Expedited Review will be provided to each IRB member at each regular convened meeting, or by mail thereafter, and an opportunity to discuss each project so approved will be available.

9.4 Full Review

(1) Applications for full review must be received 2 weeks before the meeting (unless the Chair grants a reduction of this interval). The IRB members may refuse to consider an application if they have not had sufficient time to consider it.

(2) If time permits, applications will be sent to each IRB member in advance of a meeting with a checklist of evaluation criteria. Applications consist of: LSU IRB application, proposed consent and

assent forms, copies of all instruments and questionnaires, any related grant proposals and subject recruitment material.

(3) The Chair or designate will contact the PI concerning any questions or additional information required if time permits, and present this information at the convened meeting where the project is reviewed.

(4) During the meeting other comments and questions will be encouraged. After all the issues raised have been explored, the Chair will accept a motion to approve, approve conditionally, table, or disapprove a project. A vote will be held and a majority of a quorum will be required to approve. (The numerical vote will be recorded, but those making and seconding the motion will not be recorded).

(5) Normally, the Chair will be responsible for ensuring any contingencies are met before issuing the formal approval document to the Project Director/Principal Investigator (PI).

(6) The IRB may require or invite the PI or a representative to attend. Alternatively the IRB may require or invite the PI or a representative to be available for questions by phone.

(7) Investigators associated with a project, spectators, and members having a conflict of interest will leave the room when requested to do so by the Chair, to facilitate uninhibited discussion, and may not be present for the vote.

If there are visitors or spectators present, final discussion and the vote on all projects up for review may be postponed until a convenient time during the meeting when the IRB will go into executive session.

10.0 Notification of Review Results

Investigators will be notified in writing of approvals and disapprovals by the IRB office. Any contingencies required to receive approval must be met before the approval document is issued.

11.0 Informed Consent and Assent

Informed consent is to be sought from all participants unless specifically waived by the IRB under the provisions of 45 CFR 46.

Informed consent is viewed as a PROCESS. It includes a thorough oral briefing of each potential subject, including all the elements of informed consent in 45 CFR 46, especially a discussion of any risks and potential loss of privacy; an effort to ensure the subject has fully understood what he will agree to and has had all questions answered; and signature of a consent form which documents that the subject has participated in the process of informed consent and has agreed to participate. Signature of a consent form does not by itself constitute informed consent.

In addition to parental permission, Assent is to be sought from minors of sufficient age to be able to grant it (usually 6 and older), and a minor may not be entered into a study without assent. If the child is

too young to sign the assent form, a witness to the assent process will sign the form. The IRB recognizes foster parents as having the authority to enter children in their care into studies.

A Guide to Informed Consent and a Guide to Assent are available.

12.0 Confidentiality/Anonymity

The IRB will consider whether studies should be anonymous or confidential whenever there is no compelling reason to identify the participants. The precautions to protect confidentiality in confidential studies will be documented, and the consent form will define the limitations on confidentiality.

13.0 Protocol Modification

Approval for any modification to a protocol instrument or consent document under IRB jurisdiction must be approved by the IRB (except for minor items such as correction of grammatical and typographical errors). Modification requests will be reviewed in the same way as the original proposal. Modest changes on projects initially approved by full review (such as changes in PIs, number of participants, or minor changes in instruments or consent forms) may be approved by expedited review at the discretion of the Chair.

14.0 Sponsored Program Applications

An IRB application or exemption must be sought prior to or concurrent with submittal of the application for funding. Failure to do so, or to correct the omission in a timely manner, will result in withholding the funding application, withdrawal of it by the University, or declining to accept an award until the project has IRB approval.

Multiple applications: when multiple applications are submitted to sponsors, it must be made clear to the IRB whether they are parallel submissions for the IDENTICAL scope of work, or if the scope of work differs. In the latter case the IRB will require separate applications, unless at its discretion, it determines that a single IRB application is appropriate. Subsequent applications to the same or other sponsors will require a new IRB application because the scope of work is usually altered to a lesser or greater degree. The IRB does not have the resources to compare two grant applications to determine if they are the same, and therefore usually considers each on its merits. In a new application the applicant is encouraged to explain the relationship to a previous proposal, but may not incorporate material from it by reference. The IRB reserves the right to approve a new application as a modification to a previous IRB approval if the relative scopes of work and procedures lend themselves to this solution.

15.0 IRB Meetings/Minutes

Meetings will be convened by the Chair at least twice a year; a regular schedule will be announced to satisfy the requirements of timely review. An emergency meeting may be called as necessary at 24 hours' notice. A meeting will be convened if requested by any two voting IRB members to consider a

specified topic that cannot await a scheduled meeting.

A quorum (a majority of the voting members including at least one member whose primary concerns are in non-scientific areas) is required for project approval, with a majority of those present voting to approve; an alternate may serve in the place of a voting member.

Minutes of IRB meetings will be maintained in the IRB records.

Handwritten notes and tape recordings are not the official record of the meeting, and may be destroyed after the minutes have been ratified; they are available only to those developing the formal minutes.

Minutes will comprise a summary of the business of the meeting, including a brief listing or discussion of issues raised. They are not intended to be an exhaustive or verbatim record.

16.0 Adverse Event Reporting

An adverse event is any unanticipated reaction or event which has a harmful effect on the subject which has the potential of being study-related. It may be physical, psychological or social.

Adverse events should be immediately reported whether or not the investigator believes them to be caused by the study. The investigator should report any measures taken for the benefit of the subject and to mitigate the potential of recurrences.

PI's are required to report adverse events as promptly as possible after they occur. The IRB requires an immediate report of the problem, and one or more follow-up reports detailing how it was resolved, and what steps were taken to prevent its recurrence. The Chair will evaluate each adverse event report and determine whether it needs further action beyond that taken by the investigator.

Options include seeking further information, temporarily suspending the study, discussing the matter at an emergency or regular meeting of the IRB, and then determining what further action to take, up to permanent suspension of the project. It may be appropriate to require modification of the consent form if the adverse event represents a previously unrecognized risk to participants.

17.0 Payments to Subjects

The IRB may permit payments to research subjects in return for participation, providing that such payments are not coercive in the context of the project environment.

18.0 Continuing Review

Projects are approved for a term not to exceed 12 months from the date of IRB approval.

If projects appear to present unusually great or undefinable risks, the IRB may set the approval interval

at less than 12 months. The IRB may consider whether involvement of vulnerable populations merits more frequent review. In addition, if a project has a number of project-related adverse events which cause concern, or if there are compliance or other problems associated with the project, the approval interval may be reduced so that re-review frequency is increased.

At a suitable interval before the expiration of a regular approval with greater than minimal risk, the PI will be sent a notice reminding him that he must request continuation, or report termination of the project, and submit a short report detailing any non-compliance, unreported adverse events, new knowledge that might affect informed consent, project status and progress. Exemption approvals will automatically be closed by the IRB on the expiration date unless the PI requests a continuation.

Continuing review is eliminated for all studies that undergo expedited review, unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects. The IRB will send a one-year notice to PI's regarding the status of the study. Continuing review is also eliminated for all research that has progressed to the point that it involves only data analysis or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. The reviewer must provide a rationale for conducting continuing review of research that otherwise would not require continuing review.

The IRB staff will review the reports, and prepare them for full approval. The IRB staff will prepare and present a summary of any circumstances that require special attention by the reviewers. The IRB will vote to approve/disapprove continuations in the usual manner.

If deemed necessary, the IRB may appoint one or more members to directly review a project, work with its subjects, or review the data or informed consent process on an intermittent or continuous basis. This might be done in the case of very high-risk projects, or when there are concerns about the conduct of the study.

Any serious non-compliance or study-related adverse event(s) will be reported to the Institutional Official.

19.0 Study Closure

Studies will automatically be closed by the IRB if it is approved via exempt review, expedited review, or when research progresses to the point that it involves only data analysis or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

20.0 Sanctions

The IRB may temporarily or permanently suspend a project at any time, and this suspension may not be overridden at any level in the institution (45 CFR 46). The IRB may take this action in a wide variety of circumstances, including the following, or if there is any other serious concern for the well-being of the subjects or for the reputation of the University. A study suspension must be reported to the Institutional Official and to OHRP.

If the IRB determines that an investigator is deliberately or continuously out of compliance with this Guide, with 45 CFR 46 or with the University's Assurance with OHRP, or has failed to adhere to stipulations of the IRB, or finds that the welfare of subjects is unacceptably at risk, the matter may be reported to the Institutional Official, with or without a recommendation for specific action. The Institutional Official may then recommend disciplinary action to the President.

It is necessary to emphasize that repeated or willful violations of federal laws and University policies regarding use of human subjects in research are an extremely serious matter indeed. In such a circumstance, the IRB has the authority to refuse to approve further research with human subjects by an investigator.

The University has a variety of options for disciplinary action, consistent with PS-36; such action could range from a letter of reprimand to termination.

21.0 Notification of Non-compliance

Any serious or continuing noncompliance with LSU's Assurance or 45 CFR 46 of which the IRB becomes aware shall be reported by the IRB to the Institutional Official, and if required, thence to OHRP.

Adverse events that are determined by the IRB to be study-related and which result in serious harm (physical, psychological or social) to a subject shall be reported to the Institutional Official, who shall determine if a report to OHRP is required or advisable; he will also determine what reporting within the University administration is required.

Nothing in this document shall be construed as limiting the authority of the University, the Institutional Official, or the IRB members in their duty to protect the interests of human subjects, as provided in 45 CFR 46 and other pertinent regulations.

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