Lane Community College
Institutional Review Board
Charter and Standard Operating Procedures

August 23, 2010

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INTRODUCTION

Lane Community College's Institutional Review Board (IRB) reviews federally supported research proposals which involve human subjects. The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, or the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants. In short, the IRB acts to ensure that the individuals involved in the project are treated ethically.

Principal Investigators (PIs) seeking to conduct federally supported research involving human subjects may not solicit subject participation or begin data collection until they have obtained clearance by the Lane Community College Institutional Review Board. Some federally supported research projects involving human subjects are exempt from IRB approval requirements, and others might only need an expedited, rather than a full review.

INSTITUTIONAL AUTHORITY

This Charter and Standard Operating Procedures establishes and empowers the Lane Community College (Lane) Human Subjects Protection Committee. Currently, Lane has one committee, registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board (IRB00007393 and Federal Wide Assurance # FWA00016209). This committee is hereinafter referred to as "the IRB."

PROCEDURE FOR SELECTING/ APPOINTING IRB MEMBERS

Recruitment of new members will be overseen by the Grants Office, Chief Academic Officer's office (i.e., Vice President), and IRAP. Members are officially appointed by the President or President's designee, generally the Chief Academic Officer, and reported to OHRP.

Members will serve for a three-year term. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

THE IRB'S FUNCTIONAL RELATIONSHIPS

The IRB functions administratively through the Office of Institutional Research, Assessment and Planning. This structure provides for administrative coordination for the IRB with the various

academic and administrative units at Lane. The IRB advises and makes recommendations to the President, to policy and administrative bodies, and to any member of the Lane community on all matters related to the use of human subjects in research.

DEFINITIONS

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

BASIC PRINCIPLES FOR RESEARCH INVOLVING HUMAN SUBJECTS

The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** ("The Belmont Report") created by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. Therefore, the following principles apply to all federally supported research involving human subjects at Lane Community College to ensure that adequate safeguards are provided:

1) Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
2) Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3) Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

4) Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.
5) Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
6) Participation of a human subject in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
7) All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted review ***prior*** to their initiation or ***prior*** to initiating any changes to the project. Continuing research programs are subject to periodic review, to be carried out no less often than once a year. Primary investigators will receive this information on the application form.

IRB PURPOSE

The primary purpose of the IRB is to protect the rights and welfare of human subjects used in federally supported research. The IRB safeguards individuals involved in federally supported research by ensuring that:

1) risks have been considered and minimized;
2) the potential for benefit has been identified and maximized;
3) research-volunteers are provided with substantial information about the study and volunteer only after being provided with legally effective informed consent;
4) that all private information will be handled with confidentiality; and
5) that research is conducted in an ethical manner and in compliance with established standards.

AUTHORITY AND SCOPE OF THE IRB

The IRB reviews all federally supported projects and programs involving human subjects in accordance with this Charter and Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines. The IRB has the following authority:

1) All federally supported projects and programs involving human subjects (except for research exempted or waived in accordance with section 101(b) or 101(i) of the common Rule) will be given full review by the majority of the IRB who will then either approve, require modifications in, or disapprove research activities.
2) The IRB provides continuing advice and counsel to personnel engaged in activities involving human subjects.
3) The IRB has approval authority of human subject protocols and can disapprove, modify, or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further review to determine whether it is in compliance with college policies and procedures. The Director of Institutional Research, Assessment and Planning may not *approve* the non-exempt research if it has not been approved by the IRB.

4) The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.
5) The IRB has authority to suspend or terminate approval of a study or to place restrictions on a study when this is deemed to be in the best interests of the subjects in that study.
6) The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved project especially in cases where the consentee is from a vulnerable population.
7) The IRB has the authority to access and to make copies of records related to any research approved by the IRB for any reason (or another body under an IRB Authorization Agreement), regardless of the location of those records. Where feasible, appropriate notice will be given of the need to review, copy, or duplicate records while being sensitive to causing the least inconvenience or disruption of ongoing research.

MEMBERSHIP OF THE IRB

The membership of Lane's IRB is controlled by the following provisions:

1) The IRB is composed of at least five voting members. Alternates and nonvoting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting.
2) The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of Lane regulations, relevant law, ethical standards, and standards of professional practice. The IRB may consult with specialists to review proposals for which additional expertise is needed, but the specialists may not vote.
3) The IRB must include both men and women, at least one member whose primary concerns are in the science, technology, engineering and math (STEM) areas, one whose primary concerns are nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with Lane.
4) No person shall be excluded from serving on the IRB based on sex, marital status, sexual orientation, age, family relationship, race, color, or national origin.

MANAGEMENT OF THE IRB

1) The IRB Chair is the Director of the Office of Institutional Research, Assessment and Planning. The Chair has authority to sign all IRB action items.
2) The IRB Vice Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Chair and has authority to sign all IRB action items in the absence of the Chair.
3) All IRB members are required to undergo formal training at the time of their initial appointment and complete a Training Verification Form Training can be found at:
    a. http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp
    b. for NIH proposals http://ohsr.od.nih.gov/cbt/nonNIHpeople.html

   c. http://www.sinclair.edu/about/offices/grants/compliance/irb/operations/
   d. http://phrp.nihtraining.com/users/login.php
   e. http://projects.northseattle.edu/humansubjects/training.html
   f. IRB guidebook provided by OHRP at http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
4) IRB members must complete the Training Verification Form once every three years.
5) IRB members do not receive compensation for their service.
6) Liability coverage for IRB members is provided through Lane's liability insurance coverage, whether the IRB member is an employee of Lane.
7) Consultants with competence in special areas may be used when deemed appropriate.

CONFLICTS OF INTEREST POLICY AND PROCEEDURE

Conflict of Interest for IRB Member

It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. PIs shall not be involved in the selection of IRB members. For further guidance, members can also refer to the Board of Education, Board Policy Number D.080, *Conflict of Interest* http://www.lanecc.edu/presoffc/board/policies/D080.htm.

If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters to which they are assigned immediately upon receipt to determine whether they have a conflict.

An IRB member is said to have a conflicting interest whenever that IRB member, spouse, or dependent child of the member:

1) is an investigator or sub-investigator on the project;
2) has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest;
3) acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4) has identified him- or herself for any other reason as having a conflicting interest.

IRB member(s) who have a real or perceived conflict of interest may remain in the meeting room during the discussion of the matter at the discretion of the IRB Chair in order to provide answers to questions and to clarify research. However, said member must leave the meeting room for deliberations and actions/votes on the matter.

Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions on matters for which they have, or may be perceived to have, a potential conflict of interest.

IRB REVIEW: GENERAL

The IRB will encounter three types of applications for review: the "Exempt Project Form," the "Expedited Review Form," or the "Full Board Review Form." Any disagreement between the PI and the IRB Chair regarding the type of research must be resolved by the full IRB. PIs will be notified of the IRB decision by the Chair.

Generally, for applications that do **not** fall under the exempt category, the IRB shall:

1) require that information given to subjects as part of informed consent is in accordance with the law and may add requirements as they deem necessary for the protection of the rights and welfare of subjects. (See more on informed consent on page 15.)
2) notify PIs and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval.
    a. If modifications are required, the IRB will detail the necessary changes and allow the PI to update application and resubmit for final approval.
    b. If the IRB disapproves a research activity, it shall give the reason for its decision and allow the PI an opportunity to respond in person or in writing.
3) conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.
4) The IRB will inform PIs via the application form that:
    a. **changes** in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects;
    b. any serious or ongoing problems are to be reported promptly to the IRB.
5) determine which studies need verification from sources other than the investigators that no material changes have occurred since previous IRB review. The types of studies which will require outside source verification are:
    a. complex projects involving unusual levels or types of risk to subjects;
    b. projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and
    c. projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.
6) report any serious or continuing noncompliance by an investigator, or any suspension or termination of activities, promptly to the IRB Chair and the Human Protections Administrator who will take appropriate remedial action including, but not limited to:
    a. appropriate reporting to the granting agency in a timely fashion.
    b. suspension or termination of research project.

IRB REVIEW: EXEMPTED RESEARCH

Under federal regulations, certain types of research are exempt from IRB review. The IRB Chair, not the investigator, shall make the determination as to whether a project is or is not exempt. To obtain an exemption, an investigator must submit an "Exempt Project Form" citing the specific exemption category and providing justification for the exemption. The IRB Chair will review the form and either approve it as an exemption or will explain to the PI why the project is subject to expedited or full review instead.

Exempt types of research include the following:

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

IRB REVIEW: EXPEDITED

Under federal regulations certain types of research qualify for an *expedited* review. These are activities that either

1) present *no more than minimal risk* to human subjects and are on HHS's preapproved list (below).

NOTE: The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or stigmatizing unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

2) Involve only minor changes in previously approved research during the period for which approval is authorized.

PIs applying for expedited review must submit the "Expedited Review Form" to the IRB Chair or another member designated by the Chair. In reviewing the research, the Chair may exercise all the authorities of the IRB except he or she may not disapprove the research. A research activity may only be disapproved after full review by the IRB board. If the Chair believes full review is needed, he or she must inform the PI promptly and have the PI complete the "Full Board Review Form." If the Chair approves the research, he or she must send a copy of the approved form to each member of the IRB to keep them informed of expedited approvals.

Categorical Research Areas: The following is a list of categories of research that may be reviewed by the IRB through an expedited review when the specific circumstances of the proposed research involve *no more than minimal risk.*

(found at HHS's site http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
   (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3) Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute

citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This list refers only to research that is not exempt.)
6) Collection of data from voice, video, digital, or image recordings made for research purposes.
7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This list refers only to research that is not exempt.)
8) Continuing review of research previously approved by the convened IRB as follows:

   (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects;

   (b) where no subjects have been enrolled and no additional risks have been identified;

   (c) where the remaining research activities are limited to data analysis.

REVIEW OF RESEARCH: FULL-BOARD REVIEW

Forms for **full-board (IRB) review** must be submitted four weeks prior to the deadline for the proposal or negotiated contract. The prospective PI will submit to the IRB Chair one (1) original and the required number of copies of the "Full Board Review Form." Copies of the form are

available via the Lane IRB website. On the form, the investigator assures the IRB that he/she will follow the principles, procedures, and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy. Finally, the PI must be available to discuss the project and/or consent forms at the discretion of the IRB.

The IRB will have the majority of members present when reviewing a proposal and must include at least one member whose primary concerns are in nonscientific areas. The IRB may take one of the following actions in regard to the proposed project and consent form—approve, require modifications in, or disapprove research activities.

Approved

In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Approval of the project will be based on the following:

1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk (i.e., adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject).
2) 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).
3) 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.
4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative as defined in this document.
5) Informed consent will be appropriately documented.
6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7) When appropriate, there are adequate provisions to protect the privacy of subjects.

Requirement of Modifications

If the IRB requires modifications prior to approval, then the Chair sends a memo to the PI outlining the necessary modifications. The PI then must respond to the modifications indicated by the IRB. Upon receipt and approval of the responses, the modifications are incorporated in the application; and it is processed as *approved*.

Disapproved

If the project is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her project for another review.

REVIEW OF RESEARCH: CONTINUING REVIEW

The IRB will conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year. PIs will be informed of the annual review by receipt of a Continuing Review Questionnaire. This Continuing Review Questionnaire is to be completed and returned to the Chair of the IRB along with the informed consent document currently in use with the project under review. The PI will be notified of the action taken (e.g., Approved, Required Modifications, etc.).

The IRB Chair shall consider the following when reviewing a Continuing Review Questionnaire: changes to the research, protocol deviations, and violations since the last scheduled review; adverse event reports; reports of unanticipated problems involving risks to subjects; and, if available, data safety monitoring reports; and investigator compliance.

If the protocol and/or other documents used in the project have been amended within the past five years, the PI will be requested to submit a new application incorporating these amendments if such have not previously been submitted.

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing reviews occur annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair or Vice Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions and unless this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the project will be considered closed. Enrollment of new subjects cannot occur, nor can any data collected be used for research purposes.

ADVERSE EVENT REPORTING GUIDANCE

The Office of Human Research Protections (OHRP) recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

The IRB Committee must report to appropriate institutional officials, heads of any department or agency supporting the research, any applicable regulatory body, and the Office for Human Research Protections (OHRP) of any:

a. Unanticipated problems involving risks to subjects or others; and
b. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the Lane Community College IRB committee, the President of Lane Community College, the head of any department or agency conducting or supporting the research, any applicable regulatory body, and to OHRP.

OPERATIONS OF THE IRB

1) IRB meetings are scheduled as required by the Chair.

2) The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting.

3) The IRB Chair assigns one primary reviewer and at least one secondary reviewer for each new project, who receive the complete study documentation for review. The primary reviewer is assigned consistent with project content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned based on their expertise, lead the discussion of that project. Other IRB members review summary information only but have access to complete study documentation upon request. If external reviewers are also assigned, they must be subject to the same conflict of interest policies as IRB members.

4) Voting requirements
    A. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.
    B. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.
    C. PIs, including those who are also IRB members, may offer information and answer questions about their projects at a convened meeting but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).
    D. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to executive session, then any visitors will be asked to leave the room until the executive session has ended.

5) Appeals: The PI may appeal the decision of the IRB when a project has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more faculty and/or consultants to review the project a second time.

The *ad hoc* committee members must be acceptable to both the PI and the IRB. The project will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB. The PI will be promptly notified of actions of the *ad-hoc* committee and final action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

6) Amendments are categorized into minor changes and significant changes.
   A. **Minor modification/change** – A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. Examples of **minor changes** to a research study include, but are not limited to, the following:
      - Addition or deletion of study team members;
      - Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study;
      - Removal of research procedures that would thereby reduce the risk to subjects;
      - Addition of non-sensitive questions to unvalidated survey or interview procedures;
      - Addition of, or revisions to, recruitment materials or strategies;
      - Administrative changes to the approved documents (e.g., correction of spelling, grammatical, or typographical errors).

   B. **Significant modification/change** – A proposed change in research-related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples of **significant changes** to a study may include, but are not limited to, the following:
      1. Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.);
      2. Addition of research procedures that involve greater than minimal risk to subjects;
      3. Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
      4. Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

   C. Level of Review for Amendments:
      - Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed, either by the screening committee or by the full IRB. However, if an amendment by the screening committee is determined to increase the level of risk beyond minimal risk, the screening committee will refer the amendment to the full IRB.
      - Minor modifications/changes may be reviewed and approved using an "administrative approval" process. Administrative approval may be given by the IRB Chair. Such approvals are then put on the agenda of the next IRB or screening committee, as appropriate, for concurrence.

7) Annual Reporting: The chair will provide a report of activities each year to the President and appropriate designees.

8) Grievances: The IRB shall be informed of all grievances (e.g., of a research subject against a PI), and, if requested, the board will act in an advisory capacity.

COOPERATIVE ACTIVITIES

Cooperative activities relating to human subjects are those which involve Lane Community College and another institution. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the law. With the approval of the funding agency, institutions can enter into joint review arrangements or rely upon the review of another IRB using an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties. Furthermore, Lane Community Collage may collaborate with another institution that does *not* have an FWA as long as the funding agency approves.

RECORD REQUIREMENTS

The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1) Copies of all research proposals reviewed and accompanying documents including: scientific evaluations, approved sample consent documents, progress reports and reports of injuries to subjects.
2) Detailed **minutes** of IRB meetings that show the following:
    - members present (any consultants/ guests/others shown separately).
    - results of discussions on debated issues and record of IRB decisions, including the basis for requiring changes in or disapproving research;
    - a written summary of the discussion of controverted issues and their resolution.
    - record of voting (showing votes for, against, and abstentions).
    - documentation on all four required findings when approving an informed consent modification/ waiver.
3) When Chair or designee is performing an expedited review, he/she must record his/her findings, if any, and attach them to the form for record-keeping.
4) Records of continuing review activities.
5) Copies of all correspondence between IRB and the investigators.
6) List of IRB members as listed in the FWA.
7) A copy of the Charter/ Operating Procedure
8) Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

All forms submitted or retained as evidence of informed consent must be preserved by the investigator indefinitely. Should the PI leave Lane, signed consent forms are to be transferred to the IRB Chair.

PRINCIPLES OF INFORMED CONSENT

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Basic elements of informed consent:

1) A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2) A description of any reasonably foreseeable risks or discomforts to the subject;
3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent: when appropriate, one or more of the following elements of information shall also be provided to each subject:

1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable;

2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3) Any additional costs to the subject that may result from participation in the research;
4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6) The approximate number of subjects involved in the study.

Modification or waiver of informed consent: An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

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 IRB can also allow modifications, or even waive the informed consent requirement if:

1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
2) The research could not practicably be carried out without the waiver or alteration.

DOCUMENTATION OF INFORMED CONSENT

Informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Informed consent can be presented to subjects in one of two ways:

1) Written: PIs may provide a written consent document that embodies the elements of informed consent above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.
2) Read: A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually

obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Waiver of Documentation: An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.