POLICY MANUAL

VOLUME V

Academic Policies

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Academic Policies

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5.0 Introduction

Volume V of the *Lynn University Policy Manual* has been written and designed to answer most of the questions that might be asked about the University's academic programs and services, as well as its academic, admission, and registration policies. It supersedes all previous academic related policies and procedures published in prior student handbooks.

The University hereby gives notice that it reserves the right to expand or delete or otherwise modify its degree programs or courses of study and associated policies, to change its rules and policies affecting the admission and retention of students or the granting of credit or degrees, to change the academic calendar, course offerings, course content, academic programs, or to alter its fees and other charges, whenever such changes are adjudged by it to be desirable or necessary. In any such case, the University will give appropriate notice as reasonably practicable under the circumstances.

Students enrolled at Lynn University are responsible for adhering to all regulations, schedules, and deadlines outlined in the University's Academic Catalog and Calendar, as well as in any volume, handbooks, or contracts pertinent to their program. Students have the further responsibility of ensuring that all graduation requirements are met. Questions on these matters shall be directed to the student's faculty advisor.

5.1 General Academic Information and Academic Program Overview

5.1.1 Academic Calendar

Please refer to the University Academic Catalog for the most current academic calendars pertaining to the Undergraduate and Graduate Programs, as well as the academic calendar for the Undergraduate Evening and Online Program ("iLynn").

5.1.2 Academic Programs

Information relating to Lynn University's academic programs can be found in the Annual Academic Catalog.

5.2 Admissions Policies

Information relating to the Lynn University Admissions policies can be found in the Annual Academic Catalog.

5.3 Academic Policies

The University's academic policies can be found in the Annual Academic Catalog.

5.4 Academic Support Services

Information relating to the Lynn University academic support services can be found in the Annual Academic Catalog.

5.5 Academic Awards and Honors

Information relating to academic honors and awards can be found in the Annual Academic Catalog.

5.6 Classroom Management Policies

5.6.1 Academic Freedom Policy for Students

Academic freedom is the right of reasonable exercise of civil liberties and responsibilities in an academic setting. It is the policy of Lynn University to give its students the freedom, within the bounds of collegial behavior, to pursue what seems to them productive avenues of inquiry, to learn unhindered by external or nonacademic constraints, and to engage in full and unrestricted consideration of any opinion. All members of the University must recognize this fundamental principle and must share responsibility for supporting, safeguarding, and preserving this freedom. Adjudication of academic related student grievances will be conducted by the Vice President for Academic Affairs.

5.6.2 Observance of Religious Holidays

Lynn University respects the rights of all individuals to observe customarily recognized religious holidays throughout the academic year. If a student intends to be absent from classes as a result of any such observance, the student should notify his/her professors in writing prior to the specific holiday.

5.6.3 Class Cancellations

On rare occasions, it may be necessary to cancel a scheduled class due to inclement weather or an instructor's inability to meet a class. Students and faculty will be notified of weather related cancellations in accordance with the University's Campus Closings and Cancellations Policy (see Volume II of the *Lynn University Policy Manual*). When a faculty member is unable to meet a class because of illness or other emergency an official notice of the cancellation will be posted outside the assigned classroom.

5.6.4 Classroom Conduct

Inappropriate behaviors including, but not limited to, swearing, shouting, intoxication, rude comments, or interruptions during class time are inconsistent with the overall character of an encouraging and challenging learning environment. Such behaviors are violations of the Student Code of Conduct.

Guidelines for Handling Disruptive Students

Should a University community member encounter a disruptive student, the student shall be asked politely, but firmly, to correct their behavior. If the student does not comply, the student may be asked to leave the classroom (or wherever the locus of the disruption). A University community member has the authority to do this if the student is acting in a disruptive manner. If the student refuses, Campus Safety and the Vice President for Academic Affairs should be notified.

5.6.5 Classroom Courtesy

Professional responsibility requires prompt and regular attendance of instructors at their classes and other assigned duties. Classes are to begin and end promptly. Students are free to assume that

a class has been canceled and leave if the instructor is not present within fifteen minutes of the usual starting time unless the instructor has established an alternate procedure.

5.6.6 Course Syllabi

Students will receive a course syllabus at the first class meeting or on the first day of an online course. Any additional handouts specifying work requirements (outlines for papers, structures for projects) distributed later in the course will be submitted for attachment to the syllabus kept on file.

5.7 Academic Administration Policies

5.7.1 Course Credit Hour Approval

The awarding of credit hours occurs at Lynn University in an effort to calculate and record students' achievement and fulfillment of requirements as they progress toward the earning of degrees and other academic qualifications at the institution. While credit hours are commonly understood to measure student work, it is important to remember that credit hours also reflect general academic learning. For all Lynn University academic programs, students must have successfully met the academic requirements with an amount of work represented in intended learning outcomes and verified by evidence of student achievement that reasonably approximate:

1. One hour of classroom or direct faculty instruction and a minimum of two hours of student work completed outside of the classroom each week for approximately fifteen weeks for a traditional semester, or the equivalent amount of work over a different period of time; or
2. For other academic activities (including laboratory work and other academic work leading to the award of credit hours), an amount of work at least equivalent to that required in the above definition, as determined by the College Curriculum and Academic Standard Committee, the applicable College Dean and the Vice President for Academic Affairs.

The following examples clarify the amount of work expected at Lynn University per week (for approximately fifteen weeks for a traditional semester, or the equivalent amount of work over a different period of time) for other academic activities:

Laboratory courses (with little outside preparation required) – Three hours of instruction or supervised student work conducted in the laboratory.

Laboratory courses (with moderate outside preparation required) – Two hours of instruction or supervised student work conducted in the laboratory, and one hour of preparation work conducted by the student.

Studio work – Two hours of studio instruction or supervised student work and one hour of student work completed outside of the studio.

Internships/practica/field experiences – Three hours of documented work completed by the student.

Field trips/educational travel – Three hours of actual student time spent engaged in learning.

Workshops – At least one hour of instruction or supervised work, and two hours of work completed by the student individually.

Distance Learning courses – Three hours representing a combination of instruction, discussion, group work and individual student work.

To ensure the reliability and accuracy of credit hour assignments, credit hour assignments for returning/ongoing courses are determined prior to each academic year by the College Dean in consultation with the program coordinator. Moreover, credit hour assignments are included as part of the Program Review cycle.

New courses will be assigned an initial credit hour allotment during the Curriculum Development process (see Volume IV of the *Lynn University Policy Manual*). The initiator of the course proposal is responsible for setting forth reasoning for a particular credit hour assignment, and this recommendation will be approved or amended along with the other elements of the course that are reviewed during the curricular change process.

5.7.2 Substantive Change Policy

Purpose

To establish the policy and procedures for reporting and review of institutional substantive change, prior to implementation.

Objective

To ensure compliance to the Commission on Colleges, Southern Association of College and Schools (SACSCOC) policy and procedures relating to substantive changes.

Definition

Substantive Change is defined by SACSCOC as a significant modification or expansion of the nature and scope of an accredited institution. Examples may include:

- Any change in the established mission or objectives of the institution;
- Any change in legal status, form of control, or ownership of the institution;
- The addition of courses or programs that represent a significant departure, either in content or method of delivery, from those that were offered when the institution was last evaluated;
- The addition of courses or programs at a degree or credential level above that which is included in the institution's current accreditation or reaffirmation;
- A change from clock hours to credit hours;
- A substantial increase in the number of clock or credit hours awarded for successful completion of a program;
- The establishment of an additional location geographically apart from the main campus at which the institution offers at least 50 percent of an educational program; or
- The establishment of a branch campus.

General Policy

All requests for substantive changes must be processed through the University's SACSCOC Liaison, within the timeframe designated by SACSCOC. No substantive change requests should be submitted directly to SACSCOC, except by the President.

Procedures

1. Deans contemplating a new program or significant change in their College's programming should contact the University's SACSCOC Liaison. If a Dean is unclear as to whether a change is substantive in nature, he/she should contact the University's SACSCOC Liaison for clarification.
2. To initiate the process, a Dean should submit a "Letter of Intent" to the SACSCOC Liaison and copy the President.
    a. The Letter of Intent should include a summary of the proposed change(s) along with the anticipated implementation date and location.
    b. The Letter of Intent should be submitted at least twelve (12) months prior to the anticipated launch date.
3. The SACSCOC Liaison will submit the Letter of Intent to the President for review. If approved, the SACSCOC Liaison will instruct the Dean to compile the required SACSCOC prospectus and/or application, as well as all required supporting paperwork to request a substantive change.
4. The SACSCOC Liaison and the Dean should coordinate their efforts in preparing the prospectus and/or application to SACSCOC. No one other than the President should submit any substantive change requests directly to SACSCOC.
5. The President or his designee will inform the Dean of the outcome of the prospectus and/or application evaluation by SACSCOC. No substantive changes to any College programming should occur prior to approval by SACSCOC.

Responsibilities of Deans

Deans are responsible for promptly notifying both the President and University's SACSCOC Liaison when seriously contemplating a substantive change to their College programming. Deans are responsible for seeking SACSCOC approval of a substantive change, prior to implementation. In addition, Deans are responsible for following the reporting requirements and timelines of the SACSCOC Substantive Change Policy.

Responsibilities of SACSCOC Liaison

The University's SACSCOC Liaison is responsible for ensuring that substantive changes are recognized and reported in a timely fashion. In addition, the SACSCOC Liaison is responsible for reviewing all documentation submitted by a Dean to ensure completeness and accuracy of data, prior to the University's official submission to SACSCOC.

5.8 Research Policies

5.8.1 Human Subjects Research (Institutional Review Board)

This Policy describes the procedures the Institutional Review Board (IRB) at Lynn University will follow when reviewing research with human subjects in compliance with federal requirements for the protection of research subjects. For information on the federal regulations, please refer to the United States Department of Health and Human Services Regulations, Protection of Human Subjects: Title 45, Code of Federal Regulations, part 46 (45 CFR 46), revised June 18, 1991,

December 28, 2000, August 14, 2002, and 21 CFR parts 50 and 56 [Food and Drug Administration Regulation on Protection of Human Subjects]. Also see the Health Insurance Portability and Accountability Act (HIPAA) of 1996; the Privacy Rule (also known as Standards for Privacy of Individually Identifiable Health Information) is in Title 45 of the Code of Federal Regulations, Part 160 and Subparts A and E of Part 164.

5.8.1.1 Purpose of the IRB

The Lynn University Institutional Review Board (IRB) is an independent ethical review committee mandated by the U.S. Department of Health and Human Services (DHHS). The IRB's purpose is to review research proposals for compliance with federal regulations and ethical principles to insure that human research subjects are adequately protected from harm, and that they give voluntary, informed consent to their participation.

The IRB and Lynn University research activities are subject to review by a variety of agencies, chief among them is the Office for Human Research Protections (OHRP). The Office of Academic Affairs, under the direction of the Vice President for Academic Affairs, is the administrative office responsible for the University's system of protections for human research participants.

5.8.1.2 Role and Authority of the IRB

The Lynn University IRB is established under authority delegated by the Board of Trustees to the President of Lynn University and under the governing federal regulations outlined above.

Vested with the ethical imperative to safeguard the rights and welfare of human subjects in research studies at Lynn University, the IRB has jurisdiction over any research project that involves or has the potential to involve human beings as the subjects of research and that is proposed to be carried out by a member of the Lynn University community (including faculty, students, staff, and administrators), or proposed to be carried out on Lynn University property, or that involves members of the Lynn University community as subjects of the research.

Specifically, the IRB has the authority to approve, require modifications, or disapprove proposals for research on human subjects conducted at Lynn University, or conducted by members of the Lynn University community (including faculty, students, staff, and administrators) so as to assure protection of human subjects in three major areas:

- The procedures do not place the subject at risk, include no unnecessary risks and minimize potential risks to subjects;
- The subject is informed about the purpose and intent of the research along with the necessary and sufficient details, including description of the risks or discomforts and the anticipated benefits, to assure voluntary and informed consent; and
- Privacy of the subjects and confidentiality of subject data are adequately protected.

Where the participants are members of a vulnerable population, the IRB determines whether appropriate additional safeguards are in place to protect the rights and welfare of these research participants.

In addition, the benefits of the research must outweigh the risks to the subjects. The IRB measures the importance and significance of the scientific knowledge potentially gained against risks to study subjects. The researcher is required to provide the supporting documentation. For Lynn

University, the IRB is the only authorized University committee to make this determination. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval includes a statement of the reasons for the IRB's action and is reported promptly to the investigator, appropriate institutional officials, and pertinent external bodies.

The IRB is responsible for review of Applications and Research Protocols required for all new research. The IRB determines intervals of periodic review (continuation/renewal), and, where appropriate, determines that adequate provisions are in place for monitoring the data collected to ensure the safety of subjects. The IRB is responsible for review of procedural revisions, advertisements to recruit subjects, and reports of adverse events and project termination. In addition, for research activities involving Protective Health Information (PHI), the IRB acts as the institution's Privacy Board (required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA)) to review and approve the proposed access, use, and disclosure of the PHI. Where applicable, The IRB will determine whether research subjects are required to sign an authorization for the use and disclosure of their PHI, or if one of the exceptions to the authorization requirements applies. Examples of these exceptions include waivers of authorization and the use of de-identified data or limited data sets.

5.8.1.3 Definitions

The following definitions shall apply to all IRB documentation and communications:

Principal Investigator means a person who has ultimate administrative and fiscal authority in conducting and coordinating a research project.

Co-Investigator means a person who conducts research for a given project but does not have ultimate administrative or fiscal responsibility.

Institution means any public or private entity or agency (including federal, state, and other agencies), and in particular Lynn University.

Legally Authorized Representative means an individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

A *Minor* generally means a person who is under the age of 18 who is not an emancipated minor except for certain purposes as specified by law.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general 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.

Research Subject to Regulation, and similar terms, is intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-

research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

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

Intervention includes both physical procedures by which data are gathered (for example, 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.

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 (for example, 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 to obtain the information to constitute research involving human subjects.

IRB means an institutional review board established in accord with and for the purposes expressed in this Policy.

IRB Approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

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.

Protected Health Information (PHI) means health information transmitted or maintained in any form or medium that: (a) identifies or could be used to identify an individual; and (b) is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and (c) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.

5.8.1.4 Statement of Research Principles

The following are the principles governing Lynn University in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research.

- Research must be justifiable for its scientific or other meaningful purpose or value.
- Even if an inquiry has scientific or other value, it must not be pursued if the benefit is outweighed by risk to the subject.
- The research must be conducted by sufficiently competent and knowledgeable people.
- The research must be conducted under a sound design, suited to the nature of the study.
- Informed consent is a process ensuring ethical conduct of research. No person should serve as the subject of research unless he or she, or an authorized or legal representative, has

given voluntary consent after being fully informed of the nature, risks, and benefits of the study and their rights as participants. Additional safeguards must be included in the study to protect the rights and welfare of subjects.

- Participation as a subject in a research study should be voluntary, and care should be exercised to ensure that subtle pressures are not used to obtain participation.
- Care must be taken throughout the duration of the research study (and sometimes beyond) to ensure against the risk of harm to subjects, either physical or emotional.
- Research must be terminated if there arises a serious risk of harm to subjects, either physical or emotional.
- The subject should be entitled to withdraw from participation in a research study at any time.

5.8.1.5 IRB Membership & Meetings

IRB Membership

IRB members are selected for their experience, expertise, diversity and breadth in backgrounds and represent individuals with primary concerns in both scientific and non-scientific areas.

The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. Additionally, the IRB shall not consist entirely of members of one profession.

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. It must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The Vice President for Academic Affairs shall appoint members to the Lynn University IRB to ensure compliance with federal and state requirements and institutional policies.

The IRB shall include at least five (5) members. The Chair is selected annually from among the sitting members of the IRB and is appointed by the Vice President for Academic Affairs. The Chair serves a one (1) year term. Service as the Chair will be limited to one year terms and will rotate amongst members of the committee. If the position of Chair becomes vacant, a new Chair shall be elected at the next scheduled meeting.

At the option of the IRB, a Vice Chair may be elected from among the IRB members to assist the Chair in performance of duties.

Members may include:

- Deans of the Colleges in the University (or their designated representatives);
- Coordinators of the Ph.D. Programs (or their designated representatives);
- The General Counsel; from a non-scientific area (or a designated representative);
- One non-affiliated University member from the community at-large: A non- affiliated member means an IRB member who is not affiliated with or employed by the University, nor part of the immediate family of a person who is affiliated or employed by the University;
- Members of the full-time teaching faculty from each of the Lynn University discipline areas;
- Representatives are elected by members of the discipline areas for a 3-year term** and must be approved by the Vice President for Academic Affairs.

Responsibilities of the Chair

The Chair shall preside over meetings of the IRB.

Each application, request or report pertaining to a research proposal shall be identified by an IRB Number that begins with the year of initial submission, followed by three digits. For example, the first application submitted in the year 2016, has the seven digit assigned IRB number of: 2006001 and the second application has the IRB number of 2016002. A record is maintained on each IRB project, appropriately labeled with an IRB number.

Assign review to IRB members for applications and research proposals and other requests or reports that do not require a convened full-board review.

The Chair shall forward all applications and IRB report forms to the Office for Academic Affairs for records maintenance at the end of the Calendar year (June 30). (See Records Maintenance)

All formal correspondence, decisions and recommendations in the name of the IRB shall include the IRB number and bear the signature of the Chair. The Chair shall forward all communications to the Office for Academic Affairs for records maintenance at the end of the Calendar year (June 30).

The Chair shall maintain a list of IRB members for each academic year and include the following: (a) a list of IRB members identified by name; (b) earned degrees; (c) representative capacity; (d) indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and (e) any employment or other relationship between each member and the institution. (See 45 CFR §46.103).

In instances where a project is funded or sponsored by the Federal Government changes in IRB membership must be reported to the Department or Agency head, unless in accord with §46.103(a), the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership must be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

The IRB will conduct at least two scheduled IRB Meetings annually. However, proposals for review will be reviewed on a continuous basis and proposals may be submitted when they are ready for review.

The Chair will forward all proposals to each IRB member no later than one week prior to convened meetings. Communications to investigators shall be made in writing, within 5 working days of the IRB meeting.

The IRB will notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. (45 CFR § 46.109)

The IRB Chair will keep all IRB members advised of actions which use the expedited review procedure and applications through regular reporting at convened meetings for approved expedited reviews, exemptions, continuation, procedural revisions, and advertisements to recruit subjects, and reports of adverse events and project termination.

Meeting Dates and Corresponding Application Deadlines

The IRB shall meet and conduct business at least twice a year, or more often at the call of the chairperson. Electronic submission of applications will be accepted on a rolling basis.

Except for where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b)(1), initial and continuing reviews of research will be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.

Procedures for IRB Meetings

Principal Investigators and Co-Principal Investigators may attend the IRB meeting upon the invitation of the Chair to provide information to the members, but they may not be present during the final discussions and vote.

IRB members may not participate in the initial review or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Examples of such conflicts of interest could include: a member of the IRB who serves as an investigator on research under consideration by the IRB; or a member who holds a significant financial interest in a sponsor or product under study.

At its discretion, the IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available to the IRB. Individuals invited to assist in review at the discretion of the IRB shall not vote.

Meetings

(45 CFR §46.115 IRB records) Attendance shall be recorded.

Agenda Items include:

- Approval of Minutes
- Approval of Agenda
- Old Business

- New Business: Reports or IRB Committee Review and Action (include Assigned IRB Number, title, and author). Provide Records of Actions, Discussion and Resolution of Controverted Issues:
    - Application and Protocol for Review of Research Involving Human Subjects for a New Project (IRB Form 1)
    - Application to Continue (renew) a Previously Approved IRB Project (Form 2)
    - Application for Procedural Revisions of or Changes in Research Protocol and/or Informed Consent for IRB Form 1 of a Previously Approved Project (IRB Form 3)
    - Report on Unexpected Adverse Event, Serious Injury, or Death (IRB Form 4)
    - Applications and Protocol for Requests for Exemptions (IRB Form 5)
    - Applications and Protocol for Expedited Reviews (IRB Form 6)
    - Request for Approval of Advertisements to Recruit Subjects (IRB Form 7)
    - Report of Termination of IRB Projects (IRB Form 8)
- Other Business
- Adjournment and Announcement of Next Meeting Date

Rules of Order

Parliamentary procedures follow Robert's Rules of Order

Quorum

A quorum of the IRB shall consist of at least 1/2 of the current membership. Furthermore, it shall consist of at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Should the quorum fail during a meeting, the IRB may not take further actions or votes unless quorum can be restored.

Voting

Voting on matters shall be by viva voce (by the voice), or "show of hands," general (unanimous) consent unless someone objects, or by request for a secret (written) ballot by any single member of the committee.

Proxy Voting. A proxy is a power of attorney given by one member of the committee to another to vote in his/her behalf.

All actions shall require affirmation of a majority of a quorum of the current membership except in the following instances where two-thirds of the majority is required.

Motions Requiring a Two-thirds of the majority include but are not limited to the following:

- Amend any Rules of Order, previously adopted;
- Suspending the Rules.

In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting

The IRB may consult outside experts, target populations, and others to assist in decision-making during the review process when deemed necessary.

5.8.1.6 Criteria for IRB Approval of Research

In order to approve research covered by this Policy, the IRB will determine that all of the following requirements are satisfied:

Risks to Subjects are Minimized

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, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. Minimal risk implies that the likelihood and degree of harm or discomfort expected as a result of the research are not greater than the risks encountered during the course of daily activity or during the course of routine physical or psychological examinations. Such risk considerations should not be limited to physical risk alone, but should also consider emotional and psychological risk, personal risk, and possible insurability risk.

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.

Selection of Subject is Equitable

In making this assessment, the IRB will 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 minors, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Investigators should detail any extra precautions taken to safeguard the rights and welfare of subject populations.

Informed Consent and Assent

Informed consent has been obtained and appropriately documented from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required set forth in the General Requirements for Informed Consent section of this Policy.

Subject Safety

Where applicable, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. The IRB will review who has been identified as having the primary responsibility for analyzing individual events to determine whether the study should be modified to minimize risk to current or future research subjects.

Privacy of Subject

When appropriate, the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Vulnerable Subjects

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as minors, 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. A full description of safeguards to ensure the fair and equitable treatment of these subjects and protect their rights and welfare can be found in the Department of Health and Human Services Office for Human Research Protections Code of Federal Regulations (see http://www.hhs.gov/ohrp/policy/populations/index.html).

Required IRB Training

Lynn University offers an IRB training course through the *https://phrp.nihtraining.com/users/login.php*. This training is up-to-date and meets the federal requirements for training in human subjects protections. Completion of this training is required for individuals participating in the IRB process, including investigators.

5.8.1.7 IRB Application Instructions

The Lynn University IRB will review and have authority to approve, require modifications in, or disapprove all research activities covered by this document. All proposals for human subjects' research must be submitted to the IRB for review and approval in accordance with the application instructions below. No involvement of human subjects may take place prior to formal, written notification from the IRB.

A submission for review by the IRB must be prepared for each research study using human subjects or human materials. All of the appropriate forms must be neatly typed and accurately completed. The IRB review cannot be accomplished unless all of the sections are completed. Any application that is not completed properly will be returned, possibly resulting in a delay in the review process.

Application materials (IRB Forms) are available online. Simply click on the appropriate form listed on the IRB website at: https://my.lynn.edu/ICS/Academics/Documents_and_Forms.jnz?portlet=Institutional_Review_Board.

Submissions to the IRB are accepted in electronic format. Please follow the instructions for completing the forms that are in PDF format.

All new research projects require the submission of IRB Form 1 (IRB Application and Research Protocol for Review of a New Project). In addition, either Form 2 (Request for Exemption) or Form 3 (Expedited Review) is to be completed and submitted along with Form 1 if the investigator believes the proposal qualifies for:

- An *Exemption* from Federal Regulations as noted in 45 CFR §46.101(b), exempt from full board or expedited review; or
- An *Expedited Review* as noted in CFR 45 §46.110, for certain kinds of research involving no more than minimal risk.

Note: Institutional Research surveys are not subject to IRB review.

5.8.1.8 Levels of IRB Review

5.8.1.8.1 Convened Full Board Review of New Research Projects

A Full-Board Review occurs when the application and research protocols (Form 1) involve more than minimal risk to research participants or vulnerable populations of research participants (other than minors when the protocol qualifies for expedited review) and are reviewed by the IRB at a convened meeting. Full board review is required for studies that involve greater than minimal risk or vulnerable populations that require special protection by the IRB. These populations include, but are not limited to: pregnant women, human fetuses and neonates, prisoners, and minors.

Examples of greater than minimal risk are:

- A clinical interventional study that randomly assigns human subjects to alternative experimental or placebo groups; and
- Studies involving sensitive information connected to personal identifiers.

Researchers intending to conduct research which will require full IRB review/discussion should submit their research protocols to the IRB Chair at least two weeks prior to the board's next scheduled meeting. All submissions to the IRB are done electronically and are immediately distributed to the committee for review. Therefore, IRB notifications are rolling. Only those proposals that do not obtain consensus votes or have an IRB member indicate that they wish a formal discussion would be held for the full board meeting. Notification from the IRB will also occur in an electronic format.

To submit a full-board research protocol to the IRB, the following materials must be submitted electronically to the IRB Chair:

- Electronically signed IRB Application and Research Protocol (IRB Form 1) - all pages must be completed;
- Consent Form and other requested materials and attachments; and
- Advertisement for Subject Recruitment, if applicable (IRB Form 7).

In determining whether an IRB application and research is subject to full IRB review, the IRB will utilize the Office for Human Research Protections decision charts (see http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html).

The IRB will attempt to review any full-IRB research proposal and respond with a decision within thirty (30) days of receipt of the proposal. When a proposal is submitted, it is checked for completeness. If not complete, it is returned to the principal investigator. If complete, it will be circulated to the members of the IRB for review at a convened meeting. At the meeting of the IRB, the proposal will be evaluated for the extent to which it provides for the protection of human subjects, demonstrates scientific merit and meets the criteria set forth in the *Criteria for IRB Approval of Research* section above. A majority of the members of the IRB must be present at a convened meeting, including at least one member whose primary concerns are in nonscientific areas. In order for the application to be approved, it must receive the approval of a majority of those members present at the meeting. The IRB chair will notify the investigator of the outcome of the full review.

5.8.1.8.2 Expedited Review of New Research Projects

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. Federal regulations make provisions for certain categories of research to be reviewed through an expedited procedure if the research involves no more than minimal risk. Expedited review is intended to enable the University to conserve administrative resources, provide timely reviews and focus the convened meetings of the IRB on those research activities involving greater risks or ethical complexities. In addition, the IRB may also use the expedited review procedure to review minor changes in previously approved research during the period covered by the original approval.

Research protocols that qualify for expedited review must meet two conditions: (a) the research must be determined to be minimal risk; and (b) all proposed research activities must be included in the list of eligible categories of expedited research as established by the DHHS for this purpose (see http://www.hhs.gov/ohrp/policy/expedited98.html). See also the Office for Human Research Protections expedited review decision chart (see http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html).

Under expedited review procedures, reviews may be carried out by the IRB Chair, or at the discretion of the Chair, by one or more experienced reviewers designated by the Chair from among members of the IRB. The expedited reviewer possess all the same authorities as the full IRB to approve, modify, or conditionally approve the proposed research activities, except the authority to disapprove a research activity. A research activity may be disapproved only after review in accordance with the ordinary, non-expedited procedure set forth in 45 CFR 46.108(b).

To submit an expedited research protocol to the IRB, the following materials must be submitted electronically to the IRB Chair:

- Electronically signed IRB Application and Research Protocol (IRB Form 1) - all pages must be completed;
- Consent Form and other requested materials and attachments;
- Completed Request for Expedited Review (Form 3); and
- Advertisement for Subject Recruitment, if applicable (Form 7)

Under normal circumstances, the Chair or other assigned reviewer(s) is able to review protocols in this category within 10 business days after receipt of a substantively complete protocol.

5.8.1.8.3 Exemption Procedures for Review of New Projects

Exempt research activities involve no more than minimal risk and may include classroom studies, surveys, observation of public behavior, the non-invasive collection of physiological data, and the analysis of existing data that involves human subjects. Research that includes both exempt and non-exempt categories is not exempt. More detailed information regarding exempt research activities may be found at 45 CFR §46.101(b) (see also http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101). Irrespective of whether a study is exempt from full review, it must meet accepted standards of protection of privacy and a subject's right to refuse participation without penalty.

IRB exemption reviews may be carried out by the IRB Chair, or at the discretion of the Chair, by one or more experienced reviewers designated by the Chair from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the

reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in CFR 45§46.108(b).

To submit an expedited research protocol to the IRB, the following materials must be submitted electronically to the IRB Chair:

- Electronically signed IRB Application and Research Protocol (IRB Form 1) - all pages must be completed;
- Consent Form and other requested materials and attachments;
- Completed Request for Exemption (Form 2) - an exemption from Federal Regulations as noted in 45 CFR §46.101(b), exempt from full board or expedited review; and
- Advertisement for Subject Recruitment, if applicable (Form 7)

Under normal circumstances, the Chair or another member, and generally not exceeding 3 IRB members, is able to review protocols in this category within 10 business days after receipt of a substantively complete protocol. In determining whether an IRB application and research is exempt from full IRB review, the IRB Chair or other IRB member will utilize the Office for Human Research Protections decision charts (see http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html). If the activity does not qualify for exemption, the IRB Chair or a designee notifies the investigator in writing or via email. If the IRB Chair, or designee, determines that an application does not qualify for exemption, the application will be processed either through Expedited Review or by full IRB review.

The IRB reserves the right to request the investigator to provide additional information concerning applications or reports.

5.8.1.8.4 Other IRB Reviews

1. Training or Center Grants

When training grants are submitted and some projects are expected to involve human subjects, the training grant will be reviewed by the IRB Chair, or at the discretion of the Chair, by the full board or by one or more experienced reviewers designated by the chairperson from among members of the IRB. A certification of IRB review and approval will be sent to the funding agency. (Note: Training and Center grants will be reviewed even though specific research projects for trainees or sub-projects are not fully described in the application. When IRB approval is provided for such applications, it will be contingent upon each project director submitting a complete or updated Application and Research Proposal (From 1) to the IRB prior to the initiation of their particular project.)

The investigator is responsible for ensuring that all subprojects supported by the training grant are also submitted for full IRB review prior to initiation. The annual continuing review of the training grant requires submission of a list of subprojects that involve human subjects and documentation that they have been reviewed by the IRB.

To submit a research protocol involving training or center grants to the IRB, the following materials must be submitted electronically to the IRB Chair:

- A copy of the complete proposal/grant as it was submitted to the funding agency;

- Electronically signed IRB Application and Research Protocol (IRB Form 1), Form 2 (Request for Exemption) or Form 3 (Expedited Review) if applicable – all pages must be completed;
- Consent Form and other requested materials and attachments; and
- Advertisement for Subject Recruitment, if applicable (Form 7)

2. Preliminary/Indefinite Plans

The IRB will preliminary review research proposals under the following circumstances: (a) where there is no immediate involvement of human participants, such as grant proposals planned for submission; or (b) where the research Application and Research Protocol (Form 1) is not complete and a preliminary review is desired. Generally, the review is conducted by the IRB Chair, or at the discretion of the Chair, by the full board or by one or more experienced reviewers designated by the Chair from among members of the IRB.

Upon completion of the review, a letter advising to proceed with the funding request, request for further information or further development of the proposal will be sent to the investigator. In cases of a funded project, upon funding, a detailed protocol describing the research (including the informed consent process and research instruments) must be reviewed and approved by the IRB (as a full, expedited or exempt study), pending the nature of the investigation.

To submit a preliminary research plan to the IRB, the following materials must be submitted electronically to the IRB Chair:

- A cover Letter requesting a Preliminary Review and Purpose;
- An electronically signed IRB Application and Research Protocol (Form 1), Form 2 (Request for Exemption) or Form 3 (Expedited Review) if applicable, all pages must be completed; and
- Advertisement for Subject Recruitment, if applicable (Form 7).

3. Application to Continue or Renew a Previously Approved Project

The IRB will conduct continuing review of research covered by this Policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research CFR 45 §46.109)(e).

The Lynn University IRB determines that adequate provisions are in place for monitoring the data collected to ensure the safety of subjects. Following initial approval, the researcher must seek review for projects at the intervals mandated by the IRB, not to exceed one year. The researcher is expected to forward Form 4 in a timely manner, allowing the IRB to review the project well before it expires, thus avoiding an interruption in research. Failure to seek continuing review may jeopardize present and future projects.

For projects that require a Convened Full-Board Review, the researcher forwards Form 4 and an updated consent form to the IRB no later than two months prior to the due date for renewal.

If a research proposal was authorized by expedited review, or the researcher believes the renewal qualifies for expedited review, the researcher forwards Form 4 and an updated consent no later than one month prior to the due date for renewal.

If a research proposal was authorized for exempt status, the researcher forwards IRB Form 4 and an updated consent no later than one month prior to the due date of the anniversary of initial approval.

5.8.1.9 IRB Action & Length of Approval

The investigator will be notified in writing (print or electronic) of the IRB's action on his/her research proposal. These actions include:

- *Full Approval*: The IRB approves the proposed purpose and design as described in the application for a period of one (1) year to conduct the approved research study. The investigator is responsible for informing the IRB in writing of any change or modification made to the study after approval is secured and/or continuing progress reports may be required.
- *Contingent Approval*: An application receiving contingent approval requires addition information or minor revision. When the requested changes have been made, the IRB Chair has the authority to provide full approval.
- *Deferred*: Applications that are deferred require significant revision and must be resubmitted for IRB review.
- *Disapproval*: This is a rare action and is taken only when, in the judgment of IRB members, the risks of the research outweigh the benefits to study participants, or other, significant problems exist specific to the proposed study.
- *Suspension or Termination*: The IRB has the authority to suspend or terminate any research project, including projects with full approval, that is not being conducted in accordance with the IRB's decisions, conditions, and requirements, or when unexpected serious harm to human subjects has been discovered. The investigator will receive a written explanation of the decision for suspension or termination. Any suspension or termination of approval will be determined by the committee as a whole, shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and appropriate University officials.

5.8.1.10 Unanticipated or Unexpected Adverse Event

An "Unanticipated or Unexpected Adverse Event" refers to an adverse event or other problem arising during the research the specificity or severity of which is not consistent with information already provided to the Lynn University IRB. Adverse events are categorized as follows:

Adverse Events - Undesirable and unintended, though not necessarily unanticipated, injuries or physical or emotional consequences for the subject.

Serious Adverse Events - Adverse events which are fatal or life-threatening; that result in significant or persistent disability; that require hospitalization, or represent a significant hazard or potentially serious harm to research subjects or the researchers and their staff.

Unanticipated Problems - Specific events experienced by subjects or developments that occur during implementation of research protocols that suggest the potential for increased risk to research subjects or the researchers and their staff.

In the event of an unanticipated or unexpected result, the investigator is required to submit a written report to the IRB via IRB Form 6. The time frame for the submission of the report is determined by the type of unanticipated or unexpected event that has occurred.

- When an adverse event is serious and unanticipated, the principal investigator must submit IRB Form 6 within 24 hours or by the end of the next working day.
- When an adverse event is serious but not unanticipated, the principal investigator must submit IRB Form 6 within five (5) working days.
- When an adverse event occurs which is not serious but is unanticipated, the principal investigator must submit IRB Form 6 within 10 working days.
- When an unanticipated problem occurs which does not meet the definition of an adverse event, the principal investigator must submit IRB Form 6 within 10 working days.

5.8.1.11 Proposed Changes to Research Protocol

The principal investigator is responsible for obtaining prior approval for proposed changes to an approved research protocol. Expedited review procedures may be used for certain kinds of research involving no more than minimal risk, and for minor changes in approved research (see CFR 45 §46.110). Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in CFR 45 §46.108(b). If the procedural change is judged to involve more than minimal risk, intentional deception, or questions pertaining to a protected population and does not meet the categories for exempt or expedited review it must be presented to a convened full review board for discussion and consideration of approval or non-approval. The IRB reserves the right to request the investigator to provide additional information concerning the application for a procedural change. After review, the IRB will send the applicant formal notification of IRB actions.

5.8.1.12 IRB Documents and Records

An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;
- Actions taken by the IRB and separate deliberations for each action;
- Minutes of all convened IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. The recusal of any IRB members because of a conflicting interest shall also be documented when recording votes on IRB actions;
- Records of continuing review activities;
- Copies of all correspondence between the IRB and the investigators;
- A list of IRB members in the same detail as described in §46.103(b) (3);

- Written procedures for the IRB in the same detail as described in §46.103(b) (4) and §46.103(b) (5);
- Statements of significant new findings provided to subjects, as required by §46.116(b) (5). CFR 45§46.116(b) (5) (Informed Consent). This is: 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;
- Required determinations and protocol-specific findings justifying those determinations for:
  - Waiver or alteration of the consent process. [45 CFR 46.116(c) and (d)];
  - Justification for the waiver of the requirement for written documentation of consent [45 CFR 46.117];
  - Research involving pregnant women, fetuses, and neonates. [45 CFR 46.204];
  - Research involving prisoners. [45 CFR 46.306];
  - Research involving children. [46 CFR 46.404-407];
  - The rationale for determining that risk associated with using a medical device in a study significant or non-significant (referred to as significant risk/non-significant risk device determinations); and
- When the expedited procedure for review is used, documentation of discussions, decisions, and findings will be included in the protocol file.

The records required by this Policy shall be retained for at least 3 years, and records relating to research, which is conducted, shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the federal department or Agency at reasonable times and in a reasonable manner when applicable.

5.8.1.13 Informed Consent

Except as provided elsewhere in this Policy, no investigator may involve a human being as a subject in research covered by this document 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 and at an appropriate reading level. 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 University or its agents from liability for negligence.

Basic Elements of Informed Consent

In seeking informed consent the following information must be provided to each subject:

- 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;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- 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
- 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:

- 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;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 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
- The approximate number of subjects involved in the study.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

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

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws, which require additional information to be disclosed in order for informed consent to be legally effective.

Nothing in this Policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Documentation of Informed Consent

Informed consent shall 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.

The consent form may be either of the following:

- A written consent document that embodies the elements of informed consent as set forth in the Basic Elements of Informed Consent section 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; or
- A short form written consent document stating that the elements of informed consent as set forth in the Basic Elements of Informed Consent section above 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.

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

- 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
- 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.

5.8.1.14 Institutional Endorsement

If a funding entity requires certification by an authorized official of Lynn University that the research involving human subjects for which application for support has been approved by an IRB, the IRB Administrator shall provide the requested information on behalf of Lynn University.

5.8.1.15 Periodic Review of the Approved Research

The principal investigator must inform the IRB in writing of the progress of the research one year after approval and, if necessary, apply for extension of the research using form IRB Form 4.

5.8.1.16 Payment to Research Participants

It is not uncommon for subjects to be paid for their participation in research, especially in early phases of investigational drug, biologic or device development. Payment to research subjects for participation in studies must not be considered a benefit. Financial incentives are often used when health benefits to a subject are remote or non-existent. The amount and schedule of payment must be presented to the IRB at the time of the initial review. The IRB will review both the amount of the payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence.

Difficult questions must be addressed by the IRB when considering payment to research subjects. For example, how much money should research subjects receive, and for what should subjects receive payment, their time, the inconvenience, discomfort or some other consideration? The IRB must consider whether any aspect of the proposed remuneration will be an undue influence, thus interfering with the potential subject's ability to give voluntary informed consent. In no case should remuneration be viewed as a way of offsetting risks; that is it should not be considered a benefit to be weighed against study risks. The level of remuneration should not be so high as to cause a prospective subject to accept risks that he or she would not accept in the absence of the remuneration. The same principle would apply to remuneration offered to parents whose children are prospective subjects.

5.8.1.17 Lynn University Students as Research Subjects

It is the University's general position that teachers should not use their own students as subjects in their research if it can be avoided. The University recognizes, however, that in some research situations, use of one's own students is integral to the research. This is particularly true of research into teaching methods, curricula and other areas related to the scholarship of teaching and learning. The following are two models of research design that may be permissible to the IRB:

- Collection of Data by Third Party: In situations where the activities to be undertaken by the students are not part of required class activities, and thus students may or may not choose to participate, the instructor/researcher should arrange to have the data collected by an independent third party, so that the instructor does not know who participated, and does not have access to the identifiable data or identity of participants for any purpose until grades have been assigned and entered; and
- Collection of Data by Instructor/Researcher: In situations where the collection of data by a third party is not feasible, the IRB may approve the research if the student provides written consent to use his or her own data, e.g., test results, papers written, homework, etc., after grades are entered.

Note: The giving of course credit or extra credit to students who participate in research as part of a course requirement will be approved by the IRB only when alternative means of obtaining credit is made available to students who do not wish to volunteer as research subjects. The IRB will carefully review these alternatives to make sure that students are not being coerced into becoming subjects. The informed consent statement must make clear the consequences of withdrawing from a project prior to completion.

5.8.1.18 Research Completion

The principal investigator must inform the IRB in writing when the research project has been completed through the completion of IRB Form 8, accompanied by study completion documents and archival records.

Research studies can be deemed completed for a number of reasons, each requiring a different degree of IRB involvement. Most often, the investigator will close the study and the IRB's role is passive, receiving study completion documents and archiving the records for the study. In some cases, the IRB must perform in a supervisory or disciplinary fashion and require that a study be ended.

5.8.1.19 Non-Compliance

The IRB is responsible for determining the validity of all allegations of noncompliance with respect to human subjects research activities conducted under the auspices of Lynn University and, if found to be non-compliant, determining whether it constitutes non-compliance that is serious or continuing in nature. If it is determined that a research protocol is not in compliance with regulations, regardless of whether it received prior review and approval by the IRB, it may direct corrective action to be taken.

There are two levels of noncompliance:

- *Serious*: non-compliance that may affect the rights and welfare of participants including: (I) conducting non-exempt human research without submitting an IRB protocol; (ii) actions that compromise confidentiality of the participants or the integrity or validity of the research; (iii) actions that harm the participants either physically, psychologically or emotionally; (iv) the use of subjects from federally identified protected groups, which were not identified on the IRB protocol; (v) failure to report serious events, unanticipated problems, or substantive changes to the proposed protocol to IRB; and
- *Continuing:* a pattern or multiple instances of non-compliance that: (I) indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others; (ii) compromises the scientific integrity of a study such that important conclusions can no longer be reached; (iii) suggests a likelihood that noncompliance will continue without intervention; or (iv) involves frequent instances of noncompliance or a failure to respond to a request from the IRB to resolve an episode of noncompliance or a pattern of minor noncompliance.

All cases of non-compliance are to be reported to the IRB Chair on an immediate basis. Reports can be made by research subjects, members of the research team or anyone else familiar with the research project.

The IRB Chair will inform the principle investigator (and sponsoring agency if applicable) that a non-compliance report has been made. The IRB Chair will also determine whether the report is serious enough to merit suspension of the research.

The IRB Chair will investigate and determine whether the non-compliance is Serious or Continuing. In the case of Serious or Continuing non-compliance, the IRB Chair will call a meeting of the full IRB. The researcher will be given the opportunity to attend the meeting to present information, but may not be present while the IRB makes its decisions. At this meeting the following will be determined:

- Whether action needs to be taken, and if so what form it will take. This can include requiring changes be made to the protocol, assigning a person to monitor the remainder of the research, requiring the researcher to undergo training, or suspension/termination of the research; and
- A recommendation on whether any sponsoring federal agencies need to be informed.

For cases of Serious or Continuing noncompliance, the IRB Chair will report to the Vice President for Academic Affairs the non-compliance and the IRB's decisions on remedial action. In cases of continuing non-compliance, the Vice President for Academic Affairs may revoke the research privileges of the individual at the University or institute other disciplinary actions. Although the IRB can suspend or terminate the research project only the Vice President for Academic Affairs may suspend the researcher's ability to conduct research.

5.8.2 Export Control

Lynn University is committed to full compliance with the laws and regulations of the United States addressing the export of certain goods, information, technology and services that are restricted for reasons relating to U.S. national security, economic interests, and foreign policy goals. This Policy is designed to provide guidance to University employees, students and other applicable members of the University community in the application of and compliance with the various complex U. S. Export Control laws.

It is the responsibility of all University employees, students and applicable community members to be familiar with this Policy and aware of export control laws that might apply to their activities, and to comply with those laws and University policy and procedures.

The export of certain technologies, software, and hardware is regulated and controlled by federal law for reasons of national security, foreign policy, prevention of the spread of weapons of mass destruction, and for competitive trade reasons. Export control laws require that a license be obtained prior to providing controlled technologies to foreign nationals from restricted countries. The following is a non-exhaustive list of situations that might trigger export control regulations:

- Shipping tangible items internationally;
- Sharing proprietary, confidential, or otherwise restricted information or software code with foreign nationals at a university or destinations outside the U.S.;
- Interactions with countries or organizations/individuals from a country currently subject to sanctions or embargo (see http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx);
- Hand carrying laptops, cell phones containing microprocessors and equipment while traveling to a foreign destination; and
- Exporting or importing items that have been designed, developed, configured, adapted or modified for a military application.

In addition, the trade sanctions/embargo regulations have additional requirements restricting transferring of "items of value" to sanctioned countries.

Many of the activities conducted by a University's employees, students or community members are exempt from these complex regulations. The federal regulations generally provide an exemption from export controls for basic or applied academic research that is published in the public domain and shared with the general research community. This broad exemption is

commonly referred to as the "Fundamental Research Exemption". This exemption provides that the conduct, products and results of fundamental research are to proceed largely unfettered by deemed export restrictions. Research that carries access, participation, or dissemination restrictions, however, will typically not qualify for the fundamental research exemption.

Notwithstanding research exemptions, in any of the circumstances listed above, or under other circumstances where there is a question whether export control laws might apply, the University requires its employees, students, and other applicable members of the University community to confer with the University's Office of the General Counsel to determine the applicability of export control laws and regulations (including the applicability of any exclusion or exemption) ***prior*** to the export, traveling to the country, and/or entering into any negotiations or agreements with the country, entity or person.

Failure to comply export control laws and regulations may result in criminal and civil penalties (incarceration and fines), as well as sanctions (fines, loss of research funding and/or export privileges) for the University. In addition, the failure to comply with this Policy may result in University discipline for the affected employee, student or University community member.

Definitions

"*Export*" means (a) an actual shipment or transmittal of items (such as equipment, hazardous material, or technology) controlled under the Export Administration Regulations (EAR) or International Traffic in Arms Regulations (ITAR) to persons and entities outside of the U.S.; or (b) any written, oral or visual release or disclosure of controlled technology, information or software to a Foreign Person either in the U.S. or outside the U.S.; or (c) any actual use or application of controlled technology on behalf of or for the benefit of any foreign entity or person anywhere.

"*Foreign Person*" means any person, corporation, business association, partnership, trust, society or any other entity or group that is not incorporated or organized to do business in the U.S. as well as international organizations, foreign governments and any agency or subdivision of foreign governments (e.g., diplomatic missions), and anyone who is not a U.S. citizen, a lawful permanent resident of the U.S. (i.e., a green card holder) or who does not have refugee or asylum status in the U.S.

EAR means the Export Administration Regulations written and promulgated by the Bureau of Industry and Security (BIS), Department of Commerce. See http://www.gpo.gov/fdsys/pkg/FR-2013-04-16/pdf/2013-08352.pdf

ITAR means the International Traffic in Arms Regulations written and promulgated by the Directorate of Defense Trade Controls (DDTC), Department of State. See https://www.pmddtc.state.gov/regulations_laws/itar.html

OFAC Regulations means regulations promulgated by the Office of Foreign Assets Control (OFAC), Department of the Treasury. See http://www.treasury.gov/resource-center/sanctions/Pages/default.aspx

Additional Information

The three main export control regulators are:

- The Department of Commerce, through BIS, for "dual-use" (i.e., used both in military or commercial applications) and commercial goods, information and technology under the EAR. Dual-use items are listed on the Commerce Control List (CCL), which can be found in the EAR: http://www.gpo.gov/fdsys/pkg/FR-2013-04-16/pdf/2013-08352.pdf
- The Department of State, through the DDTC, for defense technologies and services under the ITAR. Defense technologies are listed on the U.S. Munitions List (USML), which can be found in the ITAR: https://www.pmddtc.state.gov/regulations_laws/itar.html
- The Department of the Treasury through the Office of Foreign Assets Control (OFAC) for economic sanctions and embargoes, under Executive Orders and OFAC Regulations: http://www.treasury.gov/resource-center/sanctions/Pages/default.aspx
- Other agencies involved in export regulation include the Bureau of Customs and Border Protection, Department of Energy, Nuclear Regulatory Commission, Department of Justice, Department of Defense, Environmental Protection Agency, and Patent and Trademark Office.

In addition, a helpful tool for analyzing exclusions under the EAR for publicly available information is the Questions and Answers – Technology and Software Subject to the EAR which is found in Supplement 1 to part 734 of the EAR (http://law.justia.com/cfr/title15/15-2.1.3.4.22.0.1.13.23.html).