4.15 Thomas University Institutional Review Board Policies

The Thomas University Institutional Review Board (IRB) is charged with reviewing all research project proposals involving human subjects, or vertebrate or laboratory animal subjects, and biological or biomedical research involving recombinant DNA. The criteria for approval of such research projects or similar activities can be found in this Volume IV in this Section 4.15 of the Thomas University Policy Manual. The Steering Committee of the Faculty Senate, jointly with the Vice President for Academic Affairs, is responsible for appointing this committee as noted by the criteria in Subsection 2.8.5 of Volume II of the Thomas University policy manual. All governances of this group are enforced in part by the IRB Chairperson, the Office of Institutional Assessment, the Vice President of Academic Affairs and the Office of the President at Thomas University.

4.15.1 Policy for Review of Research Involving Human Subjects. Vertebrate Animal Subjects. or Recombinant DNA

a. Thomas University is responsible for safeguarding the rights and welfare of human subjects in any research, development, or related activity, and for assuring proper laboratory practices and the proper care of laboratory or other vertebrate animals used in research.

b. The purpose of the Thomas University Institutional Review Board (IRB), is to advise on the ethical standards of those conducting research using humans or vertebrate animals. Specifically, as specified by Title 45 Code of Federal Regulations, Subsection 46.107,and the Office for Human Research Protections' National Human Research Advisory Committee (November 2000) Chapter VI – IRB Guidebook, "Special Classes of Subjects," the Thomas University IRB regularly reviews research that involves a vulnerable category of subjects, such as children and minors, prisoners (detainees, parolees), institutionalized persons, pregnant women, handicapped persons, or mentally disabled or cognitively impaired persons, and human fetuses or human neonates, Human in vitro fertilization, Traumatized and comatose patients, Terminally ill patients, Elderly and aged persons, Minorities, Students, employees and normal volunteers, and International Research, as well as vertebrate animal subjects and biological or biomedical research involving recombinant DNA.

c. The responsibilities of the IRB include:

1. Reviewing research proposals by students, faculty, administrators, or any other external research applicants or entities, who want to conduct research at Thomas University, or on behalf of Thomas University in which human, vertebrate animal subjects, or biological or biomedical research focusing on recombinant DNA are utilized;

ii. Approving or recommending modifications based on ethical guidelines of accrediting bodies or learned societies for the discipline; and

m. Reporting to the President the completion of federal, state and other reports, where applicable.

d. Thomas University is committed to a policy of safeguarding the rights and welfare of all human and vertebrate animal subjects in research. As standards for the ethical treatment of human subjects, Thomas University accepts the principles set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in its report, *The Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (commonly known as the *"Belmont Report")* and Title 45 – Public Welfare Section 46, "Protection of Human Subjects" of the U.S. Code of the Department of Health and Human Services and the Office for Human Research Protections (OHRP)'s "Institutional Review Board Guidebook," as governed by the United States Department of Health and Human Services. As standards for the ethical treatment of vertebrate animal subjects, Thomas University accepts PL89-544, the Animal Welfare Act, and the National Institutes of Health Guide for the Care and Use of Laboratory Animals. As standards for research involving recombinant DNA, Thomas University accepts the National Institutes of Health Recombinant DNA Guidelines.

4.15.2 Submission of Applications for Research Involving Human Subjects

4.15.2.1 Definitions

a. Applicable Projects or Studies

Any person wishing to conduct research involving human subjects must submit a proposal to the Thomas University Institutional Review Board. This includes faculty and staff research, graduate student projects, and undergraduate projects, including class projects (where applicable), and external researchers, investigators or research entities. (See the noted Research Exemptions located within the below sub-section, L.ii - Exemptions.)

b. Application Submission

Research applicants may submit their research proposals to the IRB by completing an IRB Application (Appendix G1 – G3) according to research subject area and submitting the completed application to the Division Chairperson or departmental representative for IRB proposals. The application should be submitted by the applicant's Division Chairperson or departmental representative to the Chair of the Institutional Review Board.

c. Research

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of these regulations, whether or not they are supported or funded under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.(45 CFR 46.102 d)

d. Human Subject

i. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

11. data through intervention or interaction with the individual; and/or

111. identifiable private information (45 CFR 46.102t)

e. Invention

Invention 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. (45 CFR 46.102 f.2)

f. Direct Interaction or Interaction

Direct interaction or Interaction includes communication or interpersonal contact between investigator and subject.

g. Private Information

Private information includes information about behavior that occurs in a context in an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonable expect will not be made public (for example, a medical record). Private information must be individually identifiable (e.g., 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. (45 CFR 46.102 £2)

h. Vulnerable Populations

Vulnerable populations include minors, pregnant women, human fetuses, human neonates, prisoners (detainees, parolees), institutionalized persons, mentally disabled or handicapped persons.

1. Minimal Risk

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. That is, 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. (45 CFR 46.102 (i) and 46.303 (d)

J. IRB Approval

IRB approval means the determination of the Thomas University Institutional Review Board that the research that has been proposed and reviewed may be conducted at the institution or within the proposed venue external to Thomas University as described in the proposal, (as subject to the approval of the usage of the proposed external venue by the external venue's governing body), within the constraints set forth by the Thomas University Institutional Review Board and by other institutional or federal, state, or local regulations or requirements as they relate specifically to the research under scrutiny. All approved research will receive IRB Certification (see definition) of that approval.

k. IRB Certification

IRB certification means the act of issuing official notification to the principal investigator of the proposed research from the Thomas University Institutional Review Board in writing thereby indicating the approval of the proposed research, which has been reviewed and approved by the Thomas University IRB.

I. Applicable Research Defined

As defined, applicable research consists of all projects, studies or research that must be submitted to the IRB for approval and include the following:

1. In accordance to Title 45, CFR 46 Subsection 46.101 (2) of the U.S. Code, "research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in Title 45, CFR 46 Subsection 46.102 – *'Definitions,'* must be reviewed and approved, in compliance with Subsections 46.l 0 I ; 46.l 02; 46.l 07-46.117 of Title 45, CFR 46" by the Thomas University Institutional Review Board. That is, any research involving human subjects, vulnerable populations, vertebrate animals, or biological specimens to include recombinant DNA must be presented to the IRB for approval.

    a) Specifically, research involving human subjects that can be identified, directly, indirectly, or through specific identifiers linked to those subjects must receive prior approval from the IRB before any research can be conducted. (45 CFR 46.l02 a-h)

    b) Research involving human subjects that could divulge the responses of the subjects outside of the research which could possibly place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation must receive prior approval from the IRB before any research can be conducted. (45 CFR 46.l02 a-h)

    c) Research involving human subjects that could place subjects at minimal risk or greater than minimal risk must receive prior approval from the IRB before any research can be conducted.

(Please note exemptions in Subsection 4.15.1.ii.c. to follow.) (45 CFR 46.102 a-h)

d) Research involving human subjects that can be defined as a vulnerable population, such as, children, prisoners (detainees, parolees), institutionalized persons, pregnant women, handicapped persons, or mentally disabled persons, and human fetuses or human neonates must receive prior approval from the IRB before any research can be conducted. (45 CFR 46.102 a-h)

e) Research involving human subjects that are elected or appointed public officials or candidates for public office, or that federal statues requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter and includes the use of educational assessments (i.e., cognitive, diagnostic, aptitude, achievement or otherwise); survey procedures; interview procedures; or the observation of public behavior must receive prior approval from the IRB before any research can be conducted at or on behalf of Thomas University. (45 CFR 46.102 a-h)

f) Research involving human subjects that are not described here but fall within the limitations of Title 45 of the Code of Federal Regulations of Section 46 or any of the prescribed adopted governing entities noted in 4.15.1 Subsection (d) of this policy is subject to scrutiny and must be presented to the IRB for prior approval by the IRB before any research can be conducted.

11. Exemptions: In accordance with Title 45 CFR 46 Subsection (b), "research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy, unless otherwise directed through instruction of a governing administrator or administrative body of Thomas University:"

a) Research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, strategies, curricula or classroom management methods, *unless* those research methods will be in violation of Subsection 4.15.2. l (l) subparts (l) i.a) through (l) i.b); or (1) i.d) through (l) i.f) (noted above) of this policy, which would render the research non-exempt from prior IRB approval, are exempt from prior IRB approval if and only if, the degree of risk incurred by the subjects is minimal risk (see definition). However, all IRB "exempted" research must be approved by the Division Chairperson from which the research is being conducted prior to the implementation of the research study or project.

b) Research involving the use of educational assessments such as diagnostic assessments, aptitude, cognitive or achievement assessments; survey procedures; interview procedures; or observation of public behavior, unless the research methods violate subparts (l) i.a) through (I) i.b); or (1) i.d) through (l) i.f) (noted above) of this policy and involves risk to subjects that is greater than minimal risk (see definition), which would render the research non-exempt from prior IRB approval, the research is exempt from review and approval from the IRB prior to research implementation. However, the research must be approved by the Division Chairperson of the department from which the research is being conducted prior to the implementation of the research study or project.

c) Research involving the study or collection of publically available existing data, existing documents, existing records, existing pathological specimens or diagnostic specimens (or if the existing information is recorded in such a way that anonymity is preserved) is exempt from review and approval of the IRB prior to the implementation of the research project or study. However, the research must be approved by the Division Chairperson of the department, from which the research is being conducted prior to the implementation of the

research study or project.

d) Class Projects: Class projects conducted by students, faculty or staff are exempt from prior IRB approval if fill_of the following conditions apply to that class project and its design:

i) The proposed class project is a systematic investigation of which the findings of the investigation will not be presented to a wider audience through presentation and/or publication, or beyond classroom discussion bound within the limits of academic instruction, or an educational exercise or training, or professional development, none of which is intended for formalized research subject to regulation as described within this policy or regulated through federal, state, county or local laws or regulations; and

ii) The class project does not include the intended use of subjects from any of the vulnerable populations (see definition); and

iii) The class project is not designed to include the enrollment of subjects from select populations such as people of a specific ethnicity, a specific religion, or other single category of select populations; and

iv) The class project is not designed to include the technique of deception for the validity of the project; and

v) The class project is not designed to include any type of newly collected or existing analog or digital videotaping or recording, audio taping or recording, film ing, or visual or audible recording of any type; and

vi) The class project is not designed to include any type of sensitive information collection concerning: sexual behavior; criminal behavior; juvenile delinquent behavior; recreational drug usage; alcohol or drug usage; child abuse; physical abuse; immigration status; medical or psychological history; nor any other information that would be deemed sensitive or privileged in nature of the subject matter; and

vii) The class project is not designed to include the use of secondary data which includes Protected Health Information that is subject to HIPAA Privacy Act regulation; and

viii) The class project is designed as a normal part of the student's course work, supervised by the class instructor with the sole purpose of the project being the development of the student's research skills; and

ix) The class project is of no greater than minimal risk to subjects who participate in the project;

x) If Subsections i) through ix) (noted above) of this policy hold true for the class project, and the class project is designed to involve direct interaction or interaction with subjects with the intent of the interaction focusing on the training of students, or as an educational exercise or professional development for students and not formal research, the class project is exempt from IRB approval prior to the implementation of the class project;

xi) If Subsections i) through ix) (noted above) of this policy hold true for the class project, and the class project is designed to involve secondary data which has been designated as publicly available data, or anonymous data with no possible identifiers or links to indirect identifiers or de-identified data, all and any of which are intended for the training of students, or as an educational exercise or professional

development for students and not formal research, the class project is exempt from IRB approval prior to the implementation of the class project.

*All researchers, students and faculty should reference the Thomas University *Determination of Research or Similar Activity IRB Requirement Form* (Appendix H) *to* assist with the determination of whether a class project or practicum must be submitted to the IRB for approval prior to the commencement of the research or activity in question. The Thomas University IRB does not grant "retroactive" approval after research is done.

Class instructors and departments are responsible for providing the necessary training in respecting the privacy of participants and the confidentiality of data. However, taking into account the sensitivity of the information to be collected, the Thomas University Institutional Review Board (IRB) requires that fil.Lstudents conducting research involving human subjects complete the online Human Subjects Education Training available at http://ohrp-ed.od.nih.gov/CBTs/Assurance/login .asp, or the Collaborative IRB Training Initiative (CITI) available at http://www.irbtraining.org.

m. Full Committee Review Defined

A full committee review is a procedure for research that does not qualify for an expedited review (see definition) that occurs during convened Institutional Review Board meetings at which the majority of IRB members (a quorum) are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it will receive the approval of the majority of those members present at the meeting. (45 CFR 46.108 a-b)

n. Expedited Review Defined

An expedited review is a procedure for certain kinds of research involving no more than minimal risk to subjects that participate in the research study or project under scrutiny. The expedited review procedure is used to review one or both of the following types ofresearch or similar activities:

1. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized (See Addendum and Amendment form for IRB Research Proposal and Application) (Appendix I); or

11. Some or all of the research appearing on the US Department of Health and Human Services Federal Register list of categories of research that may be reviewed by the IRB through an expedited review procedure.

*Thomas University reserves the rights to restrict, suspend, terminate, or choose not to authorize an IRB's use of the expedited review procedure and will issue notice should such action be enforced. (45 CFR 46.110 a-d)

Thomas University and its governing administrative bodies reserves and retains the final right to determine if a research study or project or any of its methods merit exemption or non-exemption as described within this policy or shall be directed to scrutiny by the Thomas University Institutional Review Board prior to the conduct of any research study or project at or on behalf of Thomas University.

4.15.2.2 Expedited Review of Research or Similar Activities Involving Human Subjects

In order for a submitted application proposal with the requested status type of "expedited review" to qualify for such a review, the research noted within the submitted application must involve no more than minimal risk to the subjects, such as vulnerable populations (see definition) that will be used during the experimental process. Therefore, if the project involves vulnerable populations (see definition) as subjects, and if it involves only minimal risk (see definition) to those subjects, it may be submitted for expedited review. In this case, the IRB Chairperson or one or more experienced reviewers designated by the chairperson from among members of the IRB may review the study and finding no more than minimal risk to the subjects, may approve and certify the study, using a *Thomas University*

Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Human Subjects (Appendix Jl). If the IRB Chairperson or one or more experienced reviewers designated by the chairperson from among members of the IRB finds that the study involves risk to the subjects greater than minimal risk, the proposal will be submitted for full IRB review. If the application is approved through the use of the expedited review procedure, the IRB Chairperson will issue certification of the approval to the principal investigator of the research through the noted form aforementioned.

4.15.2.3 Full Committee Review of Research or Similar Activities Involving Human Subjects

If the submitted application proposal does not qualify for the expedited review procedure, it must be submitted for full committee review to the Chairperson of the IRB by way of the Division Chair or departmental representative for IRB proposals. The IRB Chairperson will send copies of the proposal to the other IRB members. The IRB members will review the proposal and return comments to the IRB Chairperson. The IRB Chairperson will then summarize the comments of the board, and given unanimous approval by IRB members, issue certification of approval for the study to the principal investigator of the research proposal using a *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Human Subjects* (Appendix Jl). The IRB Chairperson must have input and unanimous approval from a majority of IRB members in order to approve a study and issue certification of approval. If the majority does not approve of the research or similar activity, the principal investigator will be informed of that decision through the same avenue as noted for the receipt of approval.

4.15.2.4 Conflict of Interest for Research or Similar Activities Involving Human Subjects

Ifa member of the IRB wishes to conduct a study (or class project, where applicable) that board member may submit the appropriate proposal application for review to the IRB Chairperson. If it is determined that the application merits a full committee review, absent the member applicant, the Chairperson will submit the proposal to those appropriate IRB members for the full committee review process.

Ifthe IRB Chairperson wishes to conduct a study, the IRB Chairperson will submit the appropriate application to the Vice President of Academics for determination and certification of approval.

4.15.2.5 Denial of Approval of Research or Similar Activities Involving Human Subjects

If the study is deemed unethical according to the standards of the Federal Policy for Protection of Human Subjects (Title 45, section 46 of the U.S. Code), the Institutional Review Board and its Chairperson will reject the proposal using a *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Human Subjects (Appendix Ji).* All objections of the IRB member(s) will be outlined on the noted form and the principal investigator of the proposed research will be notified of the decision through the same avenue used to notify of the approval ofresearch.

4.15.2.6 Revisions and Resubmission of Research or Similar Activities Involving Human Subjects

If an application proposal has been rejected, the applicant may revise the proposal and resubmit it to the IRB Chairperson by way of their Division Chairperson or designated departmental representative for IRB proposals, as a newly revised IRB application with the noted status of resubmission. If the IRB Chairperson deems that all the objections outlined within the original *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Human Subjects* (Appendix Jl) have been answered, the IRB may approve the study or activity using a new *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Human Subjects* (Appendix J I).

If the original application proposal was reviewed through the expedited review procedure, and that original application was denied and resubmitted to the IRB, the IRB retains the right to review the resubmitted application

proposal as a full committee review status proposal, thereby waving the expedited application status (should the expedited status be requested during the resubmission process) of the newly revised and resubmitted application proposal for IRB review.

4.15.2.6.1 Proposal and Application Addendums or Amendments

Thomas University's Institutional Review Board is committed to assisting researchers with conducting research activities and projects in an ethical and safe manner. Should any changes outside of the original IRB proposal application occur, it is the responsibility *of the principal investigator of the original proposal and application* to submit all changes to the IRB through the use of the *Addendum and Amendment Form for IRB Research Proposal and Application* (Appendix I). If the changes in the proposal will not alter the scope of the original proposal, leading to a contradiction of the approved methods of the research, or cause the research methods to come into question in such matters as policy violations, the IRB will accept the change presented as an addendum or amendment to the original research proposal and application without further inquiry. However, should concerns arise, the IRB or its Chairperson may, after a good faith effort to resolve concerns related to the safety or ethics of a research activity or project determine that some or all of the research cannot be approved, or requires further inquiry by the IRB. All decisions with regard to research that is presented to the IRB will be rendered to the principal investigator of the original IRB application proposal in writing through the use of a new *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Human Subjects* (Appendix JI).

4.15.3 Submission of Applications for Research Involving Animal Subjects

4.15.3.1 Projects that must be reviewed

a. Any person wishing to conduct research involving vertebrate or laboratory animal subjects must submit a proposal to the Thomas University Institutional Review Board. This includes faculty and staff research, graduate student projects, undergraduate projects, all applicable class projects, and projects conducted by external researchers, investigators or research entities.

b. The applicant may submit a proposal for review by completing a *Thomas University Application for Review of Projects Involving Vertebrate Animal Subjects* form (Appendix J2). The application should be submitted to the applicant's Division Chairperson of their department, for submission to the Chair of the Thomas University IRB.

4.15.3.2 Expedited Review of Research or Similar Activities Involving Vertebrate Animal Subjects

Unless the project involves vertebrate animals in other than purely observations research, the application proposal may be submitted for expedited review. In this case, the Division Chairperson or designated departmental representative for IRB proposals may review the study or activity, and finding that the use of animals is in compliance with PH89-544, the Animal Welfare Act, and the NIH Guide for the Care and Use of Laboratory Animals, may approve the Study or activity, without the use of certification of approval from the Institutional Review Board. However, the Division Chairperson or departmental representative for IRB proposals may reserve the right to forward the application to the IRB for review (expedited or otherwise) and approval of the proposed research application, should they deem it necessary for further review to be conducted for the proposed research.

4.15.3.3 Full Committee Review of Research or Similar Activities Involving Vertebrate Animal Subjects

If the project does not qualify for an expedited review, the application proposal must be submitted for full committee review to the Chairperson of the IRB by way of the Division Chair or departmental representative for IRB proposals. The IRB Chairperson will send copies of the proposal to the other IRB members. The IRB members will review the

proposal and return comments to the IRB Chairperson. The IRB Chairperson will then summarize the comments of the board, and given unanimous approval by IRB members, issue certification of approval for the study to the principal investigator of the research proposal using a *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Vertebrate Animal Subjects* (Appendix J2). The IRB Chairperson must have input and unanimous approval from a majority of IRB members in order to approve a study and issue certification of approval. If the majority does not approve of the research or similar activity, the principal investigator will be informed of that decision through the same avenue as noted for the receipt of approval.

4.15.3.4 Conflict of Interest for Research or Similar Activities Involving Vertebrate Animal Subjects

If a member of the IRB wishes to conduct a study (or class project, where applicable), that board member may submit the appropriate proposal application for review to the IRB Chairperson. If it is determined that the application merits a full committee review, absent the member applicant, the Chairperson will submit the proposal to those appropriate IRB members for the full committee review process. If the IRB Chairperson wishes to conduct a study, the IRB Chairperson will submit the appropriate application to the Vice President of Academic Affairs for determination and certification of approval.

4.15.3.5 Denial of Approval of Research or Similar Activities Involving Vertebrate Animal Subjects

If the study is deemed unethical according to the standards of PL89-544, the Animal Welfare Act, or the NIH Guide for the Care and Use of Laboratory Animals, the Institutional Review Board and its Chairperson will reject the proposal using a *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Animal Subjects* (Appendix J2). All objections of the IRB members will be noted on the form.

4.15.3.6 Revision and Resubmission of Research or Similar Activities Involving Vertebrate Animal Subjects

If an application proposal has been rejected, the applicant may revise the proposal and resubmit it to the IRB Chairperson by way of their Division Chairperson or designated departmental representative for IRB proposals, as a newly revised IRB application with the noted status of resubmission. If the IRB Chairperson deems that all the objections outlined within the original *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Vertebrate Animal Subjects* (Appendix J2) have been answered, the IRB may approve the study or activity using a new *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Vertebrate Animal Subjects* (Appendix J2).

If the original application proposal was reviewed through the expedited review procedure, and that original application was denied and resubmitted to the IRB, the IRB retains the right to review the resubmitted application proposal as a full committee review status proposal, thereby waving the expedited application status (should the expedited status be requested during the resubmission process) of the newly revised and resubmitted application proposal for IRB review.

4.15.3.6.1 Proposal and Application Addendums or Amendments

Thomas University's Institutional Review Board is committed to assisting researchers with conducting research activities and projects in an ethical and safe manner. Should any changes outside of the original IRB proposal application occur, it is the responsibility of the principal investigator of the original proposal and application to submit all changes to the IRB through the use of the *Addendum and Amendment Form for IRB Research Proposal*

and Application (Appendix I). Ifthe changes in the proposal will not alter the scope of the original proposal, leading to a contradiction of the approved methods of the research, or cause the research methods to come into question in such matters as policy violations, the IRB will accept the change presented as an addendum or amendment to the original research proposal and application without further inquiry. However, should concerns arise, the IRB or its Chairperson may, after a good faith effort to resolve concerns related to the safety or ethics of a research activity or project determine that some or all of the research cannot be approved, or requires further inquiry by the IRB. All decisions with regard to research that is presented to the IRB will be rendered to the principal investigator of the original IRB application proposal in writing through the use of a new *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Vertebrate Animal Subjects* (Appendix J2).

4.15.4 Submission of Applications for Research Involving Recombinant DNA

4.15.4.1 Projects that must be reviewed

a. Any person wishing to conduct research involving Recombinant DNA must submit a proposal to the Thomas University Institutional Review Board. This includes faculty and staff research, graduate student projects, undergraduate projects, all applicable class projects, and projects conducted by external researchers, investigators or research entities.

b. The applicant may submit by completing a *Thomas University Request for Approval of Research Involving Recombinant DNA Form* (Appendix J3). The application should be submitted to the applicant's departmental representative, or if no such representative exists, to the respective Division Chairperson of their department, for submission to the Chair of the Thomas University IRB.

4.15.4.2 Expedited Review of Research or Similar Activities Involving Recombinant DNA

If the proposed project falls within the National Institutes of Health (NIH) Class III category -then the application proposal may be submitted for expedited review. The applicant should complete a *Thomas University Request for Research Involving Recombinant DNA application proposal* (Appendix J3). This application should firs be reviewed by the Division Chairperson or the designated departmental representative for IRB application proposals, who will then forward the application to the IRB Chairperson for review. The IRB Chairperson may deem that the submitted application proposal warrants full committee review by the IRB based upon the characteristics of the outlined proposal, and in so doing, forward the application to the IRB members, who will conduct a full committee review. Otherwise, the IRB Chairperson may approve the research using the expedited review procedure for IRB application proposals.

4.15.4.3 Full Committee Review of Research or Similar Activities Involving Recombinant DNA

Ifthe project does not qualify for an expedited review, the application proposal must be submitted for full committee review to the Chairperson of the IRB by way of the Division Chair or departmental representative for IRB proposals. The IRB Chairperson will send copies of the proposal to the other IRB members. The IRB members will review the proposal and return comments to the IRB Chairperson. The IRB Chairperson will then summarize the comments of the board, and given unanimous approval by IRB members, issue certification of approval for the study to the principal investigator of the research proposal using a *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Recombinant DNA* (Appendix J3). The IRB Chairperson must have input and unanimous approval from a majority of IRB members in order to approve a study and issue certification of approval. If the majority does not approve of the research or similar activity, the principal investigator will be informed of that decision through the same avenue as noted for the receipt of approval.

4.15.4.4 Conflicts of Interest for Research or Similar Activities Involving Recombinant DNA

If a member of the IRB wishes to conduct a study (or class project, where applicable), that board member may submit the appropriate proposal application for review to the IRB Chairperson. If it is determined that the application merits a full committee review, absent the member applicant, the Chairperson will submit the proposal to those appropriate IRB members for the full committee review process.

Ifthe IRB Chairperson wishes to conduct a study, the IRB Chairperson will submit the appropriate application to the Vice President of Academic Affairs for determination and certification of approval.

4.15.4.5 Denial of Approval of Research or Similar Activities Involving Recombinant DNA

If the study is deemed unethical according to the standards of the National Institutes of Health Recombinant DNA Guidelines, the Institutional Review Board and its Chairperson will reject the proposal using a *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Recombinant DNA* (Appendix J3). All objections of the IRB members will be noted on the form.

4.15.4.6 Revision and Resubmission of Research or Similar Activities Involving Recombinant DNA

If an application proposal has been rejected, the applicant may revise the proposal and resubmit it to the IRB Chairperson by way of their Division Chairperson or designated departmental representative for IRB proposals, as a newly revised IRB application with the noted status of resubmission. If the IRB Chairperson deems that all the objections outlined within the original *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Recombinant DNA* (Appendix J3) have been answered, the IRB may approve the study or activity using a new *Thomas University Institutional Review Board Application Response and Additional Comments Form /or Research Requests Involving Recombinant DNA* (Appendix J3).

If the original application proposal was reviewed through the expedited review procedure, and that original application was denied and resubmitted to the IRB, the IRB retains the right to review the resubmitted application proposal as a full committee review status proposal, thereby waving the expedited application status (should the expedited status be requested during the resubmission process) of the newly revised and resubmitted application proposal for IRB review.

4.15.4.6.1 Proposal and Application Addendums or Amendments

Thomas University's Institutional Review Board is committed to assisting researchers with conducting research activities and projects in an ethical and safe manner. Should any changes outside of the original IRB proposal application occur, it is the responsibility of the principal investigator of the original proposal and application to submit all changes to the IRB through the use of the *Addendum and Amendment Form for IRB Research Proposal and Application* (Appendix I). Ifthe changes in the proposal will not alter the scope of the original proposal, leading to a contradiction of the approved methods of the research, or cause the research methods to come into question in such matters as policy violations, the IRB will accept the change presented as an addendum or amendment to the original research proposal and application without further inquiry. However, should concerns arise, the IRB or its Chairperson may, after a good faith effort to resolve concerns related to the safety or ethics of a research activity or

project determine that some or all of the research cannot be approved, or requires further inquiry by the IRB. All decisions with regard to research that is presented to the IRB will be rendered to the principal investigator of the original IRB application proposal in writing through the use of a new *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Recombinant DNA* (Appendix J3).

4.15.5 Expectations of the Thomas University Institutional Review Board

a. Thomas University IRB Membership

1. (Thomas University IRB Composition): The Thomas University Institutional Review Board in accordance with the US Code of Federal Regulations, Section 46.107 is comprised of a minimum of five members with varying backgrounds to promote complete and adequate review of research.

ii. (Thomas University IRB Appointment Qualifiers): Those members of the IRB possess professional competencies of experience and expertise to sufficiently qualify the group to conduct the directive with which they are charged.

m. The IRB demonstrates diversity among its members, including consideration of ethnicity, gender, 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, as well as vertebrate animals.

1v. The IRB members possess characteristics and a knowledgebase that allows them the ability to ascertain the acceptability of proposed research in terms of applicable law, federal and state regulations, institutional commitments and regulations, and standards of professional conduct and ethical practices.

v. (Thomas University IRB Appointment): When appointment to the IRB occurs, every nondiscriminatory effort is made to ensure that the IRB does not consist entirely of men or entirely of women, or of individuals from one profession. Instead, in addition to those diversities noted within subcategory 'iii.' above, the IRB also includes a minimum of one member, who has the primary concern of scientific discovery, one member, who has the primary concerns of nonscientific areas, and one individual, who is not otherwise affiliated with the Thomas University and not a part of the immediate family of a person, who is affiliated with Thomas University.

vi. (Conflict of Interest): Members of the IRB cannot serve in the review process of any project or study, in which the member has an initial or a continuation of a conflicting interest, with the exception being, to serve in the capacity of providing factual information with regard to the study, if and only if that individual is asked by the remaining IRB members to provide such information.

b. Thomas University IRB Review of Research

1. The Thomas University IRB in accordance with 45 CFR 46 Subsection 46.109, reviews and has the authority to approve, require modifications to, disapprove, suspend or terminate all research as it is

submitted to the IRB. (The termination of research will occur for all research activities in violation of their proposed and approved application or that has been associated with unexpected serious harm to subjects following investigation by the IRB.)

11. The IRB in accordance with 45 CFR 46 Subsection 46.116 of *Informed Consent,* requires that information be given to subjects as a part of informed consent, and in those instances, where it is deemed that additional information would meaningfully add to the protection of the rights and welfare of subjects, the IRB requires that relevant additional information be provided to all participants, as it relates to this factor in regard to the individual research under scrutiny. In addition, the IRB will only allow for the waiver of informed consent or documentation in accordance with 45 CFR 46 Subsection 46.117, Documentation of Informed consent.

m. The IRB notifies the principal investigator in writing through the use of the *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests* (Appendix J1 through J3) according to research category, as to their decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity under consideration, or the exemption of proposed research from the IRB process in accordance with regulations.

1v. (Disapproval of Research): If the IRB disapproves a research proposal, a statement of those reasons for the disapproval will be noted on a *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests* (Appendix J1 through J3) according to the research category. The response form will also detail instructions to the investigator of how the investigator may resubmit their proposal, or appeal (Appendix I) and/or respond to the decision of the IRB in person or in writing.

v. The IRB reserves the right to monitor, observe and continue to review all research approved by the IRB according to the outlined risk of the implementation process and at no less than once per year. The IRB reserves the right to have an external or additional entity observe any and all approved research on behalf of Thomas University and the Thomas University IRB.

c. IRB Documentation and Records

1. When a member of the Thomas University Institutional Review Board approves or rejects a proposed study, that member shall retain a photocopy or electronic copy of the approval or rejection form for a period of not less than 10 years. Should a member who holds such records leave the IRB before the 10-year period elapses, the member shall transfer the records to the acting Chair of the IRB.

11. Copies of any federal or state reports filed by the IRB will be sent to the Office of the President of Thomas University.

m. The IRB will maintain minutes of all IRB meetings which will be in sufficient detail to include IRB member attendance at the meetings and all actions taken by the IRB.

4.15.6 Duration of Approvals

Approvals shall be valid for a period of one calendar year from the date of approval. If the project is not completed during that period, the researcher may simply resubmit the original application with a letter indicating that the project is continuing that must be accompanied by (1) a photocopy of the originally approved application and (2) a photocopy of the original response form and request an extension of the approved proposal's experimental / implementation timeframe. This request for an extension must be submitted a minimum of 30 days prior to the termination of the project's approval period. So long as there have been no changes in the study or in the ethical standards of Thomas University of the relevant discipline, the IRB may approve the extension of the study using a *Thomas University Institutional Review Board Application Response and Additional Comments Form for Research Requests Involving Human Subjects, Animal Subjects, or Recombinant DNA* (Appendices J1 through J3). At this point, the approval is extended for a period of one calendar year from the date of the new approval. If the study or the relevant research standards have changed, the study may be submitted for expedited or full committee review, as indicated in Subsections 4.15.2, 4.15.3 or 4.15.4 of this Thomas University Policy Manual.

4.16 Instructional Resources/Thomas University Library

Instructional Resources Thomas University Library

The Thomas University Library, located in the academic complex building, includes two computer labs, wireless internet, an online public access catalog, an Apple TV for educational podcasts, and the latest in educational technology to support the academic services of the university. The library has approximately 60,000 print and electronic books, 120 print periodical titles and GALILEO, Oxford, and Ovid database access. Open 60 hours per week, the library staff provides the students and faculty with reference services, library use instruction, and interlibrary loan services, as well as an increasingly updated collection.

It is the policy of the library to select the latest and most authoritative reference works in the major subject areas, up-to-date general encyclopedias, and significant biographical materials. In keeping with the objectives of the institution and with the policies of the departments, the librarians honor each faculty request within his/her own discipline and consider recommendations out of his/her own field. Recommendations and requests from students are honored when possible; these, like faculty requests, must be in keeping with the objectives of the institution.

The librarians use the approved bibliographies, catalogs, brochures, and other sources of recommendation for making additional selections. An effort is being made to secure material in such a way as to maintain balance in the fields of knowledge represented by the university curriculum.

As of January 2014, the TU Library had over 21,000 volumes on shelf and another 39,000 volumes available as electronic books, access to 278 databases, and 120 periodical subscriptions.

Faculty are reminded that the library staff is happy to conduct scheduled orientation tours of the library and will make class visits to offer bibliographic instruction. Individual reference instruction is also available to both faculty and students by appointment.