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I. LIBERTY UNIVERSITY MISSION STATEMENT

PHILOSOPHY OF EDUCATION

Liberty University is a Christian academic community in the tradition of evangelical institutions of higher education. As such, Liberty continues the philosophy of education which first gave rise to the university, and which is summarized in the following propositions. God, the infinite source of all things, has shown us truth through scripture, nature, history, and above all, in Christ. Persons are spiritual, rational, moral, social, and physical, created in the image of God. They are, therefore, able to know and to value themselves and other persons, the universe, and God. Education as the process of teaching and learning, involves the whole person, by developing the knowledge, values, and skills which enable each individual to change freely. Thus it occurs most effectively when both instructor and student are properly related to God and each other through Christ.

STATEMENT OF MISSION & PURPOSE

Maintaining the vision of the founder, Dr. Jerry Falwell, Liberty University develops Christ-centered men and women with the values, knowledge, and skills essential to impact the world. Through its residential and online programs, services, facilities, and collaborations, the University educates men and women who will make important contributions to their workplaces and communities, follow their chosen vocations as callings to glorify God, and fulfill the Great Commission.

LIBERTY UNIVERSITY WILL:

1. Emphasize excellence in teaching and learning.
2. Foster university-level competencies in communication, critical thinking, information literacy, and mathematics in all undergraduate programs.
3. Ensure competency in scholarship, research, and professional communication in all graduate programs and undergraduate programs where appropriate.
4. Promote the synthesis of academic knowledge and Christian worldview in order that there might be a maturing of spiritual, intellectual, social and physical value-driven behavior.
5. Enable students to engage in a major field of study in career-focused disciplines built on a solid foundation in the liberal arts.
6. Promote an understanding of the Western tradition and the diverse elements of American cultural history, especially the importance of the individual in maintaining democratic and free market processes.
7. Contribute to a knowledge and understanding of other cultures and of international events.
8. Encourage a commitment to the Christian life, one of personal integrity, sensitivity to the needs of others, social responsibility and active communication of the Christian faith, and, as it is lived out, a life that leads people to Jesus Christ as the Lord of the universe and their own personal Savior.
II. INTRODUCTION

The Institutional Animal Care and Use Committee (IACUC) is charged with ensuring that all vertebrate animals used in research or instruction at Liberty University are treated ethically and humanely in accordance with applicable Federal law. Federal law and university policy detail the authority of the committee to act in a manner that ensures the best possible care is given to every animal housed and used as a part of University research or instruction.

This handbook is designed to be a guide to the role of the IACUC at Liberty University, but should not be considered comprehensive or complete. For additional resources, please visit the IACUC website, www.liberty.edu/iacuc. Questions or concerns may be directed to iacuc@liberty.edu.
III. THE IACUC

MEMBERSHIP OF THE IACUC

Basic requirements of IACUC membership are outlined in both the Public Health Service Policy (PHS policy section IV.A.3.c) and the Animal Welfare Act (9 CFR 2.31 (a-b)). While each of these documents varies in its exact requirements, the Liberty IACUC has adopted the following rules to fulfill its obligations under these regulations and to establish and maintain a diverse, highly-qualified committee.

NUMBER & COMPOSITION OF MEMBERS

The IACUC will be chaired by an Associate or Full Professor of Liberty University, and shall have no less than five formal members with the qualifications listed below:

- One practicing scientist with experience in research involving animals.
- One Doctor of Veterinary Medicine with training or experience in laboratory animal medicine and with University-wide authority to direct activities involving animals.
- One member not affiliated with the University who represents the interest of the surrounding community with respect to care and use of animals in instruction and research.
- One member with expertise in a non-scientific area.
- One faculty, staff, and/or administrative professional from Liberty with experience and expertise in the care and use of animals in instruction or research.

Members are allowed to fulfill multiple roles on the committee. No more than three members from the same department can be on the IACUC at a given time. Persons on the IACUC that do not meet one of the specific designations (veterinarian, scientist, non-scientific, non-affiliated) are referred to as a “member” of the IACUC. Liberty’s IACUC follows OLAW’s guidelines regarding the selection and use of alternate IACUC members.

TYPES OF SUBMISSIONS TO THE IACUC

<table>
<thead>
<tr>
<th>TYPE</th>
<th>DESCRIPTION</th>
<th>FORMS REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Protocol</td>
<td>New research project</td>
<td>Application &amp; Appendices</td>
</tr>
<tr>
<td>Three Year Renewal</td>
<td>Continuation of the approved project beyond the 3rd year</td>
<td>Application &amp; Appendices</td>
</tr>
<tr>
<td>Annual Renewal</td>
<td>Progress report every 12 months, or as required by the IACUC</td>
<td>Annual Review Form</td>
</tr>
<tr>
<td>Amendment</td>
<td>Significant or minor change(s) to an existing protocol</td>
<td>Protocol Amendment Form</td>
</tr>
</tbody>
</table>

Forms are available on the IACUC website, [www.liberty.edu/iacuc](http://www.liberty.edu/iacuc)
The IACUC is a presidential committee at Liberty University, appointed by the President, or his designee, the Institutional Official (IO).

### IACUC ORGANIZATIONAL CHART

<table>
<thead>
<tr>
<th>President</th>
<th>Institutional Official (IO)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IACUC Chair (Associate or Full Professor at LU)</td>
</tr>
</tbody>
</table>

#### IACUC Members

<table>
<thead>
<tr>
<th>University Veterinarian</th>
<th>Practicing Scientist</th>
<th>Non-Scientific Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Affiliated Member</td>
<td>Expert in Animal Care (Small Animal)</td>
<td>Expert in Animal Care (Large Animal)</td>
</tr>
</tbody>
</table>

#### IACUC Support Staff

<table>
<thead>
<tr>
<th>Admin Chair of Research</th>
<th>IACUC Program Coordinator</th>
<th>Compliance Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vivarium Manager(s)</td>
<td>Laboratory Manager(s)</td>
<td>LUCOM Research/Grants</td>
</tr>
</tbody>
</table>
IV. AUTHORITIES & FUNCTIONS

AUTHORITY FOR ESTABLISHING THE IACUC

Liberty University’s Institutional Animal Care and Use Committee is prepared to file an assurance with the Office of Laboratory Animal Welfare (OLAW) in accordance with the PHS Policy. The committee is regulated by the USDA under the Animal Welfare Act (AWA) as well as Public Health Service (PHS) Policy. In order to ensure proper laboratory animal welfare, a partnership has been established with the Institutional Official (IO), the IACUC, the University Veterinarian, and the Investigators.

AUTHORITY OF THE IACUC

The Institutional Animal Care and Use Committee (IACUC) is the University’s central review body for matters relating to the care, use, and treatment of animals in research or classroom instruction. The IACUC’s scope includes the main Liberty University campus, campuses outside of Lynchburg, satellite facilities, cooperative units, and off-campus locations. The IACUC is responsible for the oversight of all animal care and use, and for ensuring compliance with federal, state, and local regulations. The IO and President reserve the right to suspend or disapprove research, despite IACUC approval.

The following are federally mandated functions of the IACUC, according to policies outlined in the Animal Welfare Act (9 CFR Ch. 1 Subpart C 2.31 (c) (1-8)), Guide for the care and use of Agricultural Animals in Agricultural Research and Training (Chap. 1), and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Section IV. B. (1-8)).

AUTHORITY TO INSPECT ANIMAL HOUSING FACILITIES AND THE UNIVERSITY’S ANIMAL CARE AND USE PROGRAM

An IACUC sub-committee will convene for the explicit purpose of conducting a semi-annual review once every six months. IACUC members in attendance will review and evaluate the animal care, treatment, and use program at Liberty University using the Semiannual Program Review Checklist (“The Checklist”). No member will be involuntarily excluded from participation. The documents referred to for the review will be: The Checklist, The Guide, and PHS Policy. Each IACUC member will use the Checklist during the review. Deficiencies will be classified as minor or significant. A plan of action and schedule will be devised in order to correct any identified deficiencies. The IACUC office will notify the investigator(s) of any deficiencies. Member comments and identified deficiencies will be compiled, summarized, recorded and reported to the IO in the Semiannual Report. A quorum of the IACUC will review and approve the Report prior to submission. A copy will be kept by the IACUC office on behalf of the chair. The program areas that will be evaluated during the program review include, but are not limited to: the Animal Care and Use Program Overview, Disaster Planning & Emergency Preparedness, The IACUC, IACUC Protocol Review & Special Considerations, IACUC Membership & Functions, IACUC Training, IACUC Records & Reporting Requirements, Veterinary Care, Personnel Qualifications & Training, Occupational Health and Safety of Personnel, Personal Security, Investigating & Reporting Animal Welfare Concerns.
An IACUC sub-committee will convene for the explicit purpose of conducting a semi-annual facility inspection once every six months. This sub-committee must consist of at least two voting IACUC members. Members in attendance will review and evaluate the animal use facilities using the Semiannual Facility Inspection Checklist (“The Checklist”), noting any deficiencies. Each animal room, service area, or procedure area will receive a report, regardless of whether any deficiencies were identified. At the conclusion of the inspection, any deficiencies will be classified as minor, significant, or repeat. The IACUC chair, in collaboration with the IACUC office, will provide a plan of action and schedule of completion to rectify the noted deficiencies. The findings will be provided to the investigator and/or facility manager. The IACUC office will follow-up to ensure that deficiencies are addressed on or before the dates provided in the plan of action. The deficiencies, plan of action, and date of correction will be included in the Semiannual Report to the IO, and shall be reported to OLAW, if applicable. The animal facilities that will be evaluated during the review include, but are not limited to: Terrestrial Animal Housing & Support Areas, Cage Wash, Special Facilities—Aseptic Surgery, Special Facilities—Procedure Areas, Non-Survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Contamination, Behavioral Studies.

**AUTHORITY TO PREPARE AND SUBMIT REPORTS OF THE IACUC EVALUATIONS TO THE IO**

The IACUC will submit all inspection reports to Liberty’s Institutional Officer (IO). The report includes both major and minor deficiencies, and the program review. A quorum of the IACUC voting members must sign the reports, and minority views (if any) must be submitted in writing. Such views will be duly recorded and incorporated into the final report.

**AUTHORITY TO PREPARE AND SUBMIT REPORTS TO REGULATING OR ACCREDITING BODIES ON BEHALF OF THE IO**

The IACUC will convene to review inspection results from the program evaluation and facility review. After approval by a quorum of IACUC members, the findings will be summarized in the Semiannual Report to the Institutional Official, using the template provided by OLAW. The Report will include: the date and outcome of each inspection, departures from PHS Policy or the Guide identified during inspection, IACUC-approved departures with rationale, minor, significant, or repeat deficiencies, a schedule and plan for correcting deficiencies, and any minority views. The IACUC office will maintain a copy of the Report on behalf of the Chair.

**AUTHORITY TO MAKE RECOMMENDATIONS TO THE IO REGARDING THE INSTITUTIONAL ANIMAL CARE AND USE**

Any recommendations made to the IO as a result of the Semiannual Inspections shall be communicated using the Semiannual Report. Recommendations that are made at other times shall be sent in writing (with appropriate documentation and justification) on behalf of the IACUC by the IACUC Chair or designee.
The IACUC has monthly meetings scheduled throughout the year for the express purpose of reviewing protocols and to discuss other pertinent business.

**Receipt of Protocols:** Principal Investigators will submit protocol applications to the IACUC and Attending Veterinarian simultaneously via email. The IACUC office will assign a protocol number, verify training status, and inform the PI that the preliminary review process will begin shortly.

**Veterinary & Administrative Pre-Review:** Upon receiving a protocol application, the IACUC office and the Attending Veterinarian will each review a copy of the protocol, making note of any requests for any clarifications, edits, or missing information. Once the Attending Veterinarian has completed his or her review of the study, he or she will forward any revision requests to the IACUC Office. The IACUC office will compile comments from the administrative review and veterinary review into a single document to be sent via email to the PI for revision. This process may be repeated as necessary until revisions are acceptable.

**Notification of IACUC Chair:** Once adequate revisions have been received as a result of the preliminary review process, the IACUC chair will be notified that the protocol is ready to proceed to protocol review.

**Conducting Protocol Reviews:** The IACUC Chair (or the IACUC office) will distribute pending protocols to all committee members for initial review. Discussion is recorded in the minutes in accordance with PHS Policy, IV.E.1.b. Per PHS Policy IV.2., any IACUC members involved in the protocol or those with any potential conflicts of interest must recuse themselves from any discussion or voting. For the purposes of voting, recused individuals should not be counted toward quorum. Any conflict of interest shall be recorded in the minutes. Absent members’ comments may be presented for the purpose of discussion. However, absent members cannot vote. The committee may determine that an outside consultant is needed to provide appropriate discipline-specific guidance and may invite that consultant to participate in the review and approval process.

**Full Committee Review:** The IACUC chair presides, and presents the protocols scheduled for review. In order to review protocols, a quorum of voting members must be present. Protocols that involve procedures listed in pain category E must be reviewed by the full committee. In certain cases, the IACUC Chair may request that the PI be present for the discussion. However, once deliberation begins, the PI will be asked to leave the room. After adequate discussion of each protocol, the full committee may vote in the following way: “approve”, “modifications requested to secure approval”, “defer or table”, or “withhold approval”. A voice vote will be taken, and the majority vote shall represent the decision of the committee. The outcome of the vote, and any dissenting votes, abstentions, or minority views will be recorded in the minutes.

- **Designated Member Review following Full Committee Meeting:** Per IACUC policy, a quorum of members present at the convened meeting may unanimously vote to have any requested modifications reviewed and approved by DMR following the full meeting. If
such a vote is received at the convened meeting to proceed in this manner, the IACUC Chair may appoint one or more voting members to serve as Designated Reviewers. The IACUC office shall serve as the intermediary between the Designated Reviewers and the principal investigator. Designated Reviewers may take the following actions: “approve”, “modifications requested to secure approval”, “refer protocol to full committee”. Decisions made by the designated reviewers must be unanimous. Any requested modifications must be reviewed by all designated reviewers. If designated reviewers do not agree to approve the protocol, it must be returned to full committee. Designated reviewers are not allowed to withhold approval.

**Designated Member Review (DMR):** Occurs after the IACUC Chair (or the IACUC office) distributes pending protocols to committee members for initial review, but only if no single voting member requests full review of the protocol. Members will be given one week to briefly review the protocol to determine whether they believe a full review is warranted, or if the protocol can be sent to DMR. The IACUC Chair will appoint members who are most familiar with the nature of the protocol to review the request, considering any potential for conflicts of interest. The IACUC Chair can assign any number of designated reviewers to the protocol. This process will proceed as described above in “Designated Member Review following Full Committee Meeting” with the same possible outcomes.

**Appeals Process:** If a protocol is not approved by either of the above protocol review processes, at the request of the investigator, the committee will interview the investigator and attempt to resolve any issues prior to written appeal to the IO. Should the appeal process require a written appeal to the IO, the following process will be followed:

- The IO will review the committee’s original decision to withhold approval. He or she may agree with the IACUC’s decision, or the IO may determine that further review is warranted. If the IO decides that further review is warranted, the protocol will be reviewed a second time by the IACUC. The PI and the IO will have the opportunity to provide additional information, opinions, or consultation to the IACUC. The PI must then recuse themselves from the meeting. After deliberation, the committee will decide to vote in either of the following ways: “approval” or “withhold approval”.
- In either case, a letter announcing the decision is forwarded to the investigator and the IO. The IACUC office will keep a copy of this letter on behalf of the IACUC Chair.

Principal Investigators must submit protocol amendments for review whenever a significant change to approved animal use is considered. Once received, the IACUC office will inform the PI that the amendment has been received, and the review process will begin shortly. Significant changes include, but are not limited to:

- Change in the purpose, aim, or objectives of a study
- Change in Principal Investigator
- Change or addition of a new species
- Increasing the number of an already approved species
- Adding hazardous agents
- Changing an approved procedure (duration, frequency, invasiveness)
- Adding or changing therapeutic/analgesic/anesthetic agents
• Change in housing or husbandry
• Change in the method of euthanasia

Once a significant amendment has been received by the IACUC office, the amendment will be distributed to the committee via email. The committee will be asked to respond in the same way they would for receipt of a protocol (full review or designated member review), and the amendment review process is handled in the same manner as a new protocol. These processes are described above in III.D.6.

Changes in personnel may be handled administratively by the IACUC office. The PI must submit the Personnel Amendment Form. The IACUC office will review the personnel amendment to ensure that listed individuals are properly trained, qualified, and are enrolled in Occupational Health Training.

Minor changes to a protocol may either be reviewed administratively, or by Designated Member Review, depending on the nature of the proposed change.

All amendment requests, correspondence, annual reviews, and reviewer comments shall be recorded and saved in the protocol’s file by the IACUC office.

<table>
<thead>
<tr>
<th>AUTHORITY TO APPROVE PROTOCOLS, REQUIRE PROGRESS REPORTS FROM THE INVESTIGATORS, AND OVERSEE THE CONDUCT OF THE STUDY</th>
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</table>

Notice of Approvals: The IACUC office will inform investigators of approval via email. This includes approvals for: protocols, protocol amendments, and annual reviews. A pdf of the approval letter signed by the IACUC Chair will be provided in the email. The IACUC office maintains copies of all approval letters, which may be printed and provided in hard copy at the request of the investigator, or the Grants office.

Letters include the date of approval, Principal Investigator’s full name, protocol number and title, and period of approval (three years maximum). While the approval is dated for three years, continued approval is contingent upon the successful completion of an annual review each year, prior to the anniversary of the original protocol approval.

Notice of Tabled Review: If the IACUC chooses to table a protocol review, the IACUC office will deliver the decision to the Principal Investigator via email at the conclusion of the IACUC meeting in which the decision was made. This email will include a letter signed by the IACUC Chair, detailing the committee’s rationale, and any recommendations to the PI regarding resubmission or revision.

Notice if a Protocol is Not Approved: If the IACUC chooses not to approve a protocol, the IACUC office will deliver the decision to the Principal Investigator via email at the conclusion of the IACUC meeting in which the decision was made. This email will include a letter signed by the IACUC Chair, detailing the committee’s rationale, and any recommendations to the PI regarding resubmission or revision.
Notification of the Institutional Official of Protocol Review Decisions: The IO will be notified of all IACUC action (approvals and withholdings) in a monthly report submitted by the IACUC office. This report will also include a listing of meeting minutes to include submitted protocols and amendment requests, along with a status and brief description of each.

### AUTHORITY TO CONDUCT POST-APPROVAL MONITORING ON APPROVED PROTOCOLS

**Annual Reviews:** An Annual Review must be completed by the Principal Investigator prior to the date of the first and second anniversary of the protocol’s original approval. This review shall include: the number of animals used to date, updates to personnel, unreported changes in protocol or unreported adverse events, and a summary of key developments from the past year. Investigators are reminded to submit any changes for IACUC approval prior to implementation. Annual Reviews are sent out to the committee for review, and if any issues are apparent, members may choose to discuss at a full committee meeting, or approve by DMR (See above, III.D.6 for this process). The IACUC office, upon receiving an annual review, will verify the animal use totals against the approved number, and verify the training status of any listed personnel.

**Post Approval Monitoring:** Post approval monitoring is conducted randomly throughout the life of a protocol to ensure compliance with regulations and adherence to the IACUC-approved protocol. Any identified issues will be reported to the Chair, and appropriate action will be taken to promptly correct the deficiency. If PAM identifies any issues that pose an immediate threat to the health or welfare of the animals, the University Veterinarian may take action to promptly resolve the issue.

**Three-Year Renewals:** On the third anniversary of original protocol approval, the protocol is considered expired. Should the PI wish to continue the project, a new protocol application must be submitted in advance of the expiration date. If the protocol is submitted after the third anniversary date, no further animal use is permitted, and all animals shall be transferred to a holding protocol until a new protocol is approved by the IACUC. The renewal process follows the same procedures listed above for a new protocol application.

### AUTHORITY TO SUSPEND OR TERMINATE APPROVAL OF ANY APPROVED ACTIVITY

The IACUC may suspend an activity only after review at a convened IACUC meeting. The suspension vote must be a majority vote. Depending on the nature of the activity, an emergency meeting may be called. Criteria for the suspension and any timelines for resolution are recorded in the minutes, along with the final vote and any minority views. The IACUC office will send a letter to the PI via email informing them of the decision. The IACUC Chair and IO will be copied on the email. Upon receipt, the IO will review the action taken by the IACUC and provide a preliminary written report to OLAW. The IO has the ability to impose additional sanctions for lifting the suspension. If a suspension was the result of significant animal welfare concerns, the PI must assure the IACUC that steps have been taken to reduce the likelihood of recurrence prior to the suspension being lifted. Once suspension has been lifted, the IO shall
submit a final report to OLAW describing the reasons for suspension and the actions taken to remedy the situation.

Investigators with a pattern of non-compliance may be denied IACUC review or the use of animals for teaching/research at the discretion of the IACUC Chair, University Veterinarian, IO, and/or PI’s Department Chair. Those with a history of ignoring the provisions of the Guide or the Animal Welfare Act are also covered under this statement.

**AUTHORITY TO REVIEW CONCERNS INVOLVING ANIMAL CARE AND USE**

All new and existing IACUC personnel will be informed of how to report concerns involving animal care and use at the University, including the Whistleblower policy. Information for reporting concerns is available on the IACUC website. Other mechanisms that enable individuals to report concerns include: reporting posters prominently displayed in each animal laboratory, in-person, by phone, or by email to the IACUC Chair, IACUC Office, University Veterinarian, Principal Investigator, or Lab/Facility Manager.

- **How Concerns are Handled & Reported by the IACUC:** Once received, all reported concerns will be promptly forwarded to the IACUC Chair. The IACUC Chair or designee will investigate the claim by promptly contacting the responsible party. If the Chair finds that a claim is substantiated, the Chair or designee shall promptly contact the responsible party with a plan to correct the deficiency. If the claim does not warrant immediate attention, the complaint will be reported at the next convened IACUC meeting for discussion. If the Chair or designee determines that the complaint poses an immediate threat to the well-being of the animals, the Chair will convene the committee to present the problem for discussion. The IACUC, in consultation with the university veterinarian, will review the matter, make recommendations, and vote on appropriate action up to and including a vote to suspend the activity either indefinitely, or until the problem is resolved. The IACUC chair, the attending veterinarian, and/or the IO will take appropriate action(s) to ensure that there is no reprisal against the individual reporting the concern. Significant animal welfare issues will be promptly reported to the IO, who may choose to take additional action. As required, OLAW, USDA, and other funding agencies will be notified of the deficiency and timeline for correction.