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IRB FORM 6

LYNN UNIVERSITY INSTITUTIONAL REVIEW BOARD
REPORT OF UNEXPECTED ADVERSE EVENT, SERIOUS INJURY OR DEATH

The following information must be submitted in typed or word processed format. Fill in all information lines. If information is not applicable, indicate by answering "N/A."

Principal Investigator:
IRB Project Number (if previously approved):
Date of initial IRB approval, if applicable (for this project):
Initial Review: Full ☐ Expedited ☐ Exempt ☐ (*Check the appropriate item)*
Date of most recent IRB renewal, if applicable (for this project):
Today's Date:
Project Title:
Date of Adverse Event, Injury or Death:

Report changes only to items listed below since last IRB review (initial or continuing).

Principal Investigator: (*Full name and educational credentials)*	
Principal Investigator: Address	
Project Title:	
Students: *Specify Degree Program* (Employees enrolled in degree programs, complete this item.)	
Employee: *Specify Position and Employment Unit*	
Phone Number: (Work)	
Phone Number: (Home)	
Phone Number: (Mobile)	
Fax Number:	
E-mail:	
Faculty Sponsor (If applicable)	
Phone Number: (Work)	
E-mail:	
Co-Investigators (Associate or Collaborating Investigator(s): Names, titles and address. If list is extensive, insert on a separate page.	

Policy and Procedure

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 Principal Investigator is responsible and must adhere to the policies and procedures for emergencies and reporting of adverse events explained therein. Problems include unanticipated side effects or adverse reactions from participation in the project and any injuries. If any emergency occurs, the investigator(s) should first call 911 and be prepared to provide the following information to the dispatcher: (1) type of injury and what assistance is needed, (2) number of victims, (3) the location and instructions on how to get there, and (4) their name and telephone number. The investigator(s) should then promptly notify, in writing, the sponsor (if applicable), supervising vice president (if applicable) and chair of the Institutional Review Board. The written notifications shall be submitted within seven days of the adverse event. Submit a copy of IRB Form 6, responding to items as applicable.

The IRB reserves the right to request the investigator to provide additional information concerning the report of an adverse event. After review, the IRB will send the applicant formal notification of IRB actions.

Site of injury, unexpected adverse event or serious problem:
Did the event(s) described below occur at this institution? Yes ☐ No ☐
Or was the information describing the event(s) provided by outside sources (such as the sponsor or others)? Yes ☐ No ☐ (If yes, attach relevant documents from sponsor or others).
If this was an emergency, was 911 called? Yes ☐ No ☐ (if yes, by who [specify below].)
When were the following people first notified of the event (specify date and time, and method of notification) and what actions were you advised to take? Sponsor / Supervising Vice President / Chair of the IRB / Others (please specify):
In the opinion of the Principal Investigator, was the injury or event caused by the research article, device or procedure? No ☐ Yes ☐ Probably ☐ Possibly ☐ Indeterminate ☐
NATURE OF INJURY TO SUBJECT: Describe the medical nature of all events suffered by the subject.
CAUSE OF INJURY, UNEXPECTED ADVERSE EVENT OR SERIOUS PROBLEM: Describe the cause or possible cause of the adverse events, serious injury or death.
TREATMENT OF SUBJECT: Describe the treatment (if any) for the subject's injury and the result or anticipated result.
Was the research suspended? Yes ☐ No ☐. If yes, describe and provide rationale. (Other than suspension, were other actions implemented with respect to the research protocol? Yes ☐ No ☐ If yes, describe:
PROPOSED CHANGES IN PROTOCOL & INFORMED CONSENT: As a result of the injury or events described above, are changes necessary in the protocol? Yes ☐ No ☐ and/or in the consent form? Yes ☐ No ☐ If answer is yes for either, attach revised protocol (or relevant portion thereof) or revised consent in its entirety highlighting the relevant changes (revisions) and a copy of the consent form in use prior to the revisions. In addition, the Principal Investigator was also submit Form 5.

SIGNATURES (To sign the document, click on the pink tab below and follow the computer prompts)

_____

Signature of Sponsor (required for students) Date

_____

Name Position Academic Unit/Department

_____

Signature of Sponsor (for non-doctoral employees) Date

_____

Name Position Academic Unit/Department

_____

Signature of Vice President (for staff employee) Date

_____

Name Position Academic Unit/Department

_____

Signature of College Dean (for faculty) Date

_____

Name Position Academic Unit/Department

NOTE: Reports without all requested information will be returned without IRB review and places the project at risk for termination.

Principal Investigator:
Project Title:

DO NOT WRITE BELOW THIS LINE: FOR IRB USE ONLY

IRB Project Number:
REPORT OF UNEXPECTED ADVERSE EVENT, SERIOUS INJURY OR DEATH
Initial Review: Full ☐ Expedited ☐ Exempt ☐ Date of most recent continuation approval: _____
IRB ACTION BY IRB CHAIR OR ANOTHER MEMBER OR MEMBERS DESIGNATED BY THE CHAIR
Report (s): Accepted/Approved _____ Accepted/Approved w/provision(s) ____ Referred For Convened Full-Board Review _____
Comments:
Consent Required: No ☐ Yes ☐ Not Applicable ☐ Written ☐ Signed ☐
Consent Form Revised: No ☐ Yes ☐. If yes, the Consent forms must bear the research protocol expiration date of _____. Date for Application to Continue/Renew is as noted on initial application or most recent renewal
Other Comments:
IRB Reviewer: _____ Title _____ Date _____
IRB Reviewer: _____ Title _____ Date _____
IRB Reviewer: _____ Title _____ Date _____
IRB Reviewer: _____ Title _____ Date _____
IRB Reviewer: _____ Title _____ Date _____

Name of IRB Chair (Print) _____

Signature of IRB Chair_____Date:_____

IRB ACTION by the CONVENED FULL BOARD *If Applicable*
Date of IRB Review of Report of an Adverse Event_____
IRB ACTION: Accepted/Approved _____ Accepted/Approved w/provision(s)_____
Suspension of Project _____ Termination of Project _____ * *Submit copies of a Summary Report (See Form 8: Termination of IRB Project)
Comments:
Consent Required: No ☐ Yes ☐ Not Applicable ☐ Written ☐ Signed ☐
Consent Form Revised: No ☐ Yes ☐. If yes, the Consent forms must bear the research protocol expiration date of _____.
Date for Application to Continue/Renew is as noted on initial application or most recent renewal
Other Comments:

Name of IRB Chair (Print) _____

Signature of IRB Chair_____Date:_____