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BRIRC STEP-BY-STEP SUBMISSION AND REVIEW PROCESS

<u>Step 1</u>- Project Coordinator (PC)/Primary Investigator (PI) completes all portions of the BRIRC Application Form. This includes the submission of copies of detailed protocols/analytical methods that will involve the use of the listed agent(s). All investigators (including students) that will be handling materials will need to complete the "BRIRC Researchers" course at www.citiprogram.org. Instructions can be found at

http://research.latech.edu/about/compliance review boards/biosafety and radionuclide institutional review committee/

<u>Step 2</u>- Have the Center Director/Facility Director/Department Head/Budget Unit Head of the applicant, or *designee*, complete a "Laboratory Safety Survey" of each laboratory in which this project is to be conducted and determine that the laboratory and the participants in this project are in compliance with the policies and procedures set forth in the Louisiana Tech University Safety Manual and the Louisiana Tech University Laboratory Safety Manual. Attach the most recent completed Laboratory Safety Survey (-ies) to the application.

Step 3- PC/PI obtains signature of the appropriate Budget Unit Head.

Step 4- PC/PI submits the **signed** Application and an electronic version to Arlene Hill, Research & Partnerships Office (ahill@latech.edu; Campus Box 52), with a request that the review be expedited or to be considered by the entire BRIRC. Ms. Hill will log in the proposal and assign it a BRIRC proposal number. The proposal is checked for form completeness.

<u>Step 5</u>- The application will be <u>checked for all the requested information and appropriate signatures are on the cover page</u> and that the submission includes <u>the appropriate BRIRC proposal form</u>. It may be immediately recommended that an incomplete proposal be denied further review by the BRIRC. If the submission appears to be complete electronic copies of the proposal will be forwarded to the appropriate committee "Facilitator" based on the relevant technical area of expertise. A record of each notification letter sent will be kept.

<u>Step 6-</u> The facilitator checks the technical content of the proposal for completeness. The facilitator may recommend that an incomplete proposal be denied a full review by the BRIRC. Once the proposal has been deemed to be technically complete (or not), the facilitator will notify the Research & Partnership Office to send the appropriative "receipt" notification letter within five working days of receipt. A record of each notification letter sent will be kept.

Step 7- If the PC/PI has requested an expedited review, the facilitator initially reviews the proposal to determine if the biological agent(s), radionuclide, etc. involved in the project poses only "minimal risk" to humans, other animals, plants or the environment and whether all project-specific policies and procedures are in place for the project to proceed in a safe fashion. (NOTE: ALL PROPOSALS WHICH ARE ASSOCIATED WITH ANY FEDERAL FUNDING SOURCE, IN PART OR IN WHOLE, MAY NOT BE EXPEDITED ACCORDING TO FEDERAL GUIDELINES.)

The speed of expedited reviews depends on the complexity of the study and whether the project conforms to the appropriate safety guidelines, or what additional revision may be required. The facilitator can recommend approval of the project, request revisions or additional information or a referral to the full BRIRC. The facilitator alone cannot recommend disapproval of a study, and an expedited review does not eliminate the need for input from the entire BRIRC. The expedited review process is simply a method to speed up the approval process for educational or simple proposals.

If the Project Coordinator/Primary investigator requests that the proposal be considered by the entire BRIRC <u>or if the expeditor</u> <u>determines that the project involves more than a "minimal risk"</u>, copies of the proposal along with recommendations and comments from the facilitator are sent to all members. Skip to Step 10.

Step 8 - If a proposal is expedited and recommended by the facilitator, copies will be transmitted electronically to each member of the BRIRC for their review. Members of the Committee are requested to submit their approval of the project, or requests for additional information or clarification from the PC/PI, or specific reasons for denial, to the Research & Partnerships Office (Arlene Hill), electronically, within five working days of receipt of the proposal.

Step 9 - If the proposal is expedited, reviewed and recommended by the committee with twelve or more 'yes' votes, the proposal and the comments of all reviewers and any follow up responses between the facilitator and the PC/PI will be forwarded to the Chief Officer of Research & Innovation (CRIO) for review. "No" votes become part of the record with reasons listed, and are made available to the CRIO. He/she may approve the project, "as is" or request additional information from the PC/PI or facilitator, prior to his/her approval. Once approved by the CRIO, the appropriate notification letter is sent.

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<u>Step 10</u> – If the proposal was not expedited, the proposal is considered by the entire Committee at the next convened meeting, it and the comments of each Committee member and any follow up responses between a committee member and the Program Coordinator will be forwarded to the CRIO for review. Twelve "yes" votes are required for recommendation of approval. "No" votes become part of the record with reasons listed, and are made available to the CRIO. The CRIO may approve the project, "as is" or request additional information from the PC/PI or the appropriate committee member, prior to his/her approval. Once approved by the CRIO, the appropriate notification letter is sent. If the proposal is denied by the CRIO, a notification letter will be sent with a detailed explanation. A user may wish to modify their project and re-submit a new application for consideration by the BRIRC.

Step 11- Previous approval of any expedited reviews are entered into the record at the next BRIRC meeting. Copies of all correspondence relating to the Project will be kept on file in the Research & Partnership Office for a minimum of 5 years.

ADDITIONAL INFORMATION

The BRIRC meets two-three times per year to review applications. Applications must be submitted at least thirty (30) days prior to a meeting to be considered at that meeting. Decisions of the Committee will be communicated to the PC/PI and other appropriate individuals within 10 days of the committee recommendation and the approval of the CRIO. NO PROJECT CAN BE INTITATED UNTIL THIS WRITTEN APPROVAL IS PROVIDED TO THE PC/PI.

BRIRC approval of a project is for one (1) calendar year from the date of approval. The project is to be terminated at that time unless the BRIRC receives a request for continuance. Modification of an approved project is STRICTLY PROHIBITED without prior Committee approval of these modifications. Request for continuance or protocol modification must be received by the Research & Partnership Office 30 days prior to the renewal date or before initiation of the modified protocol.

BRIRC meetings are open to the public.