Policy

In accordance with UAB Institutional Review Board (IRB) Policies and Procedures, scientific review of all new investigator-initiated research is required at the department level. This policy applies to all levels of IRB review - full, expedited, and exempt. Note that the UAB Gene Therapy Project Review Panel will continue to review all gene therapy protocols.

This departmental review process will be handled according to the following guidelines:

1. The Principal Investigator (PI) shall identify at least one expert reviewer, who is not an investigator or supervisor on the project, to review the research protocol and to provide comments and/or recommendations for revision prior to IRB submission. The reviewer(s) may be selected from within the department faculty or may be external to the department; however, at least one reviewer must hold primary faculty status at UAB. The reviewer(s) should have the appropriate expertise to review the protocol in relevant areas such as the scientific merit and design of the proposed research, use of human participants in psychological research, and health care or safety-related issues. The PY 101 Subject Pool Coordinator (Dr. Ed Cook; ecook@uab.edu) should be included among the reviewers if the project will recruit using the PY 101 Participant Pool and/or award PY 101 research credits for participation.

2. The PI is responsible for making all appropriate contacts with potential reviewers, providing them with copies of all necessary materials, and negotiating the time frame for review in order to allow time for submission to the department and the IRB prior to any designated due date.

3. Forms. Each reviewer should be provided with a complete copy of the human subjects protocol (HSP), any consent form(s), all other materials that will be submitted to the IRB, and the Department of Psychology’s Reviewer Comment Form (which is attached to this policy document). The reviewer provides written feedback to the PI on the Comment Form and signs it. After receiving the reviewer’s feedback the PI completes and signs the bottom of the form, indicating that all of the reviewer’s comments and recommendations have been addressed. The PI also completes the Department of Psychology Scientific Review Form which documents the departmental review and serves as a cover sheet for all reviews for submission to the Department of Psychology and the IRB. Note that the Department of Psychology Scientific Review Form replaces the IRB’s Protocol Oversight Review Form (PORF).

4. When the review and any revisions are completed, the PI submits the entire IRB submission packet, including the HSP, consent form, and additional materials and forms including the Scientific Review Form and one or more Reviewer Comment Forms, to Mary Frances Thetford, (mthetford@uab.edu), in 415 Campbell Hall. Ms. Thetford reviews the materials for completeness and compliance and forwards them to Dr. Ball for her final review and signature. Please allow at least 24-48 hours for this process to be completed. It is recommended that principal investigators contact Ms. Thetford at least two days in advance to notify her of a forthcoming protocol for review.

5. As Department Chair, Dr. Ball acknowledges by signature that the protocol and associated materials have received the necessary reviews and are approved for IRB submission. Materials are then returned to Ms. Thetford, who notifies the PI that the paperwork is signed and the materials are ready to be picked up from the Department of Psychology office for delivery to the IRB office.
Renewals for Departmental Scientific Review

Scientific review is not necessary for IRB renewals and amendments unless there are significant changes to the protocol, such as the addition of a new subject population or substantial modification to the protocol such as changing or adding an aim or analysis to an already approved study.

The addition or removal/replacement of key personnel on the protocol, including graduate students, does not require additional scientific review but does require a written notification to the IRB via a protocol Amendment. Additional forms and certification of training may also be required for new personnel, consistent with IRB policy. The PI is responsible for compliance with these IRB requirements.
UAB Department of Psychology Scientific Review Form
(Must be included with all protocol submissions to the UAB IRB)

The Principal Investigator identifies at least one scientist, who is not a co-investigator or supervisor on the project, to review the research protocol and provide comments and/or suggestions prior to IRB submission. Results of the review(s) should be attached to this form for departmental review and IRB submission. (Based on UAB Notice of IRB Submission Policy Change Dated June 3, 2003)

Project Title: __________________________________________________________

Principal Investigator: (please print or type) __________________________________________________________

Doctoral Program (for graduate students; BN, LDPP, or MDPY): ____________

Exempt ☐ Expedition ☐ Full ☐ New Submission ☐ Renewal with Significant Changes ☐

This protocol has been reviewed at the ☐ Departmental Level ☐ External Reviewer(s) [outside the department]

Reviewing Scientist(s): The following individuals have provided comments and suggestions to the Principal Investigator on this project:

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I have received and addressed all comments and recommendations from the reviewer(s).

__________________________ Date
Principal Investigator Signature

This project is approved by the Department of Psychology for submission to the UAB-Institutional Review Board for formal institutional review.

__________________________ Date
Mary Frances Thetford, M.Ed.
Executive Program Director, Psychology

__________________________ Date
Karlene K. Ball, Ph.D.
University Professor and Chair, Department of Psychology

Rev. 3/26/2013
UAB Department of Psychology
Reviewer Comment Form
(Please print or type; must be included with all protocol submissions to the UAB IRB)

Title of Protocol:________________________________________________________________________

Name of Reviewer:__________________Signature__________________Date______________

Comments/Recommendations: (print or type)

Investigator Response:___________________________________  __________________
Investigator Signature     Date

________________________________________________________________________
Investigator Signature       Date