



## New Study Submissions

1. You received an IRBNet email **your study is APPROVED**. What should you do?
  - Log into IRBNet to read your approval letter, and print the IRB stamped consent form.
  - It is important to note whether there any IRB requirements or limitations of your approval.
  - The maximum number of subjects will be listed.
  - The study approval date and expiration date will be listed.
  - Make sure you use the actual IRB stamped consent form.



Institutional Review Board  
Division of Research  
777 Glades Rd.  
Boca Raton, FL 33431  
Tel: 561.297.0777  
[fau.edu/research/researchint](http://fau.edu/research/researchint)

Michael Whitehurst, Ed.D., Chair

DATE: June 11, 2015

TO: FAU Owl, PhD

FROM: Florida Atlantic University Social, Behavioral and Educational Research IRB

IRBNET ID #: 123456-1

PROTOCOL TITLE: [123456-1] Reviewing IRB Approval Letters through the use of IRBNet

PROJECT TYPE: *New Project*

ACTION: APPROVED

APPROVAL DATE: 06/11/2015

EXPIRATION DATE: 06/11/2016

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # A1

Thank you for your submission of New Project materials for this research study. The Florida Atlantic University Social, Behavioral and Educational Research IRB has APPROVED your *New Project*. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

- This study is approved for a maximum of 100 subjects.
- It is important that you use the approved, stamped consent documents or procedures included with this letter.
- **\*\*Please note that any revision to previously approved materials or procedures, including modifications to numbers of subjects, must be approved by the IRB before it is initiated.** Please use the amendment form to request IRB approval of a proposed revision.
- All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use





2. You received an IRBNet email **your study has Modifications Required**. What should you do?

- Log into IRBNet to read the details of the Modifications Required Letter.
- Review the letter including the instructions on how to submit your response.
- Go to “Other Tools”, then “Forms and Templates” and locate “Form 5 – Response to IRB concerns.”
- Prepare your response, upload Form 5, and any revised documents requested.
- Ask the PI to review and sign the response, and then submit the package.

Additional information is available on IRB web page - **Frequently Asked Questions (IRB FAQs):**

[http://www.fau.edu/research/researchint/irb\\_faqs.php](http://www.fau.edu/research/researchint/irb_faqs.php)



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DATE: June 11, 2015

TO: FAU Owl, PhD

FROM: Florida Atlantic University Social, Behavioral and Educational Research IRB

PROTOCOL #: 123456-1

PROTOCOL TITLE: [123456-1] Reviewing IRB Modifications Required Letter using IRBNet

SUBMISSION TYPE: New Project

REVIEW TYPE: Expedited Review

**ACTION: MODIFICATIONS REQUIRED**

Thank you for your submission of New Project materials for this research study. This submission has received Expedited Review based on the applicable federal regulation. The Florida Atlantic University Social, Behavioral and Educational Research IRB has determined that the following MODIFICATIONS are REQUIRED in order to secure approval:

1. There is a discrepancy between the application form and the protocol regarding...
2. Please revise the consent form as follows a) ....
3. Clarify the following in the protocol a) ... b)...

Please provide your response to the IRB using Form 5 (RESPONSE TO IRB) which can be downloaded from Forms and Templates. In addition, attach any documents (revised consents, protocol, etc.) the IRB may have requested.

Use the following steps:

