



**EAST CAROLINA UNIVERSITY**  
**University & Medical Center Institutional Review Board**

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[www.ecu.edu/ORIC/irb](http://www.ecu.edu/ORIC/irb)

## Notification of Continuing Review Approval

From: Biomedical IRB  
 To: [Joseph Houmard](#)  
 CC:

[Josh Yang](#)

Date: 3/16/2018

Re: [CR00006737](#)

[UMCIRB 13-002234](#)

Characterization of Myotubes to be used for a Bioassay.

I am pleased to inform you that at the convened meeting on 3/14/2018 12:15 PM of the Biomedical IRB, this research study underwent a continuing review and the committee voted to approve the study. Approval of the study and the consent form(s) is for the period of 3/14/2018 to 3/13/2019.

The Biomedical IRB deemed this study Greater than Minimal Risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Document	Description
Cell studies medical history form(0.01)	Data Collection Sheet
Consent document (approval for use of stored samples)(0.01)	Dataset Use Approval/Permission
ECU J&J main consent 5-5-15 clean copy with corrections(0.01)	Consent Forms
ECU JJ Genetic consent V.2 May 2015.doc(0.02)	Consent Forms
ECU JJ Main consent V.3 5-5-15 mods.doc(0.02)	Consent Forms
ECU/ J&J Protocol June 2014(0.01)	Study Protocol or Grant Application
ECU/J&J PTC Oct. 5, 2016(0.01)	Study Protocol or Grant Application
ECU-J&J Obese non-surgery flyer(0.01)	Recruitment Documents/Scripts
ECU-J&J PTC V.3 may 5, 2015(0.01)	Study Protocol or Grant Application
Flyer to focus on diabetic enrollment for females 20-65, BMI over 40.(0.01)	Recruitment Documents/Scripts
Houmard Cell Culture Consent (covers future research)(0.01)	Consent Forms
J&J Myotubes Flyer Non-surgery group Oct 2015(0.01)	Recruitment Documents/Scripts
J&J Myotubes Main consent V.4 4/19/16(0.01)	Consent Forms
J&J Myotubes PTC V.4 4/19/16(0.01)	Study Protocol or Grant Application
J&J Proposal April 2014(0.01)	Study Protocol or Grant Application
J&J Student group consent (updated locations)(0.01)	Consent Forms

Document	Description
Menstrual Cycle Recall:(0.01)	Surveys and Questionnaires
Recruitment flyer (lean group)(0.01)	Recruitment Documents/Scripts
Recruitment flyer: Add Virginia Koonce as coordinator(0.01)	Recruitment Documents/Scripts

The following UMCIRB members were recused for reasons of potential for Conflict of Interest on this research study:

J. Yang

M. L. Pories

The following UMCIRB members with a potential Conflict of Interest did not attend this IRB meeting: None

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IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418  
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418