

IRB Chair Letter

IRB Chair Letter

Check here to enter IRB Chair LetterComment: 6-14-17 Dually signed IAA is attached to this function. RPMS

Signed By:



IRB Chair

**Institutional Review Board Authorization Agreement between
Institution A (Auburn University) and
The Food and Drug Administration (FDA)**

Pursuant to 45 C.F.R. 46.114, Institution A (Auburn University) and the FDA are entering into this agreement for Institute A (Auburn University) to conduct IRB review of the research protocol identified below, which are jointly conducted by Institute A (Auburn University) and the FDA.

Name of Institution or Organization Providing IRB Review (Institution A):

Auburn University
Federal Wide Assurance (FWA) # FWA00001104
IRB Registration # IRB00001220, IRB00009019

Name of Institution Relying on the Designated IRB (Institution B):

Food and Drug Administration
FWA #: 00006196
IRB Registration #: 00000580

The FDA will rely on the IRB of Institution A (Auburn University) for review and continuing oversight of its human subjects research described below. This agreement is limited to the following specific protocol(s):

Name of Research Project: “Generic Drug Substitution in Special Populations”

Protocol Number 1: 16-357 EX 1609

Protocol Number 2: 17-140 EP 1705

Name of Principal Investigator (Institution A): Dr. Jingjing Qian

Name of Principal Investigator’s (Institution A) Institute or Center:

Auburn University Harrison School of Pharmacy

FDA’s RIHSC # 17-037D

Name of Principal Investigator/Sponsor/Contact (FDA): Dr. Zhong Wang

The review performed by Institution A’s IRB will meet the human subject protection requirements of the FDA’s OHRP-approved FWA. Institution A’s IRB will follow written procedures for reporting its findings and actions to appropriate officials at the FDA. Relevant minutes of IRB meetings will be made available to the FDA upon request. The FDA remains responsible for ensuring compliance with the IRB’s determinations and with the terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request

Authorizing Signatory Institutional Officials

Institution A

John M. Mason, Jr.

May 24, 2017

Date

John M. Mason, Jr., PhD
Vice President for Research and Economic Development
202 Samford Hall
Auburn AL 36849-5112
Phone: 334-844-4784
Fax: 334-844-5971
jmason@auburn.edu

FDA



6/9/17

Date

Luciana Borio, MD
Acting Chief Scientist
Bldg. 1, Rm 3317
10903 New Hampshire Ave
Silver Spring, Maryland 20993
Phone: 301-796-4880
Fax: 301-847-3536
Luciana.borio@fda.hhs.gov