



February 29, 2016

By Overnight Delivery and Return Receipt Requested

Ms. Mildred Joyce Heinrich
Texas Applied Biomedical Services
dba Texas Applied Biotechnology Research Review Committee IRB
dba TABS Research Review Committee IRB # 1
12101 Cullen Boulevard, Suite A
Houston, Texas 77048

Order of Disqualification

Dear Ms. Heinrich:

I have reviewed the administrative record of the regulatory disqualification proceeding involving TABS Research Review Committee Institutional Review Board, dba Texas Applied Biotechnology Research Review Committee IRB, dba TABS Research Review Committee IRB # 1 (TABS RRC).¹ After reviewing information available to the Food and Drug Administration (FDA), I have determined that TABS RRC has repeatedly failed to comply with the regulations set forth in 21 CFR Part 56 and that TABS RRC's noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation. In accordance with 21 CFR Part 16 and § 56.121, Texas Applied Biomedical Services is disqualified. Under authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's Decision disqualifying TABS RRC.

The basis for this disqualification determination is set forth in detail in the attached Commissioner's Decision.

FDA will not approve an application for a research permit for a clinical investigation that is under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and FDA may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB or conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in 21 CFR § 56.123.

An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or

¹ TABS Research Review Committee is the name under which this IRB is registered with the Office of Human Research Protections, Department of Health and Human Services:
<http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc>. This IRB has conducted business as Texas Applied Biomedical Services, Texas Applied Biotechnology Research Review Committee IRB, and TABS Research Review Committee IRB #1

IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in 21 CFR Part 56.

With regard to any ongoing clinical investigations conducted under the review of TABS RRC, the FDA Center with jurisdiction over the product being studied in each clinical investigation shall determine any additional actions to be taken with regard to each ongoing clinical investigation reviewed by TABS RRC. Actions may include, but are not limited to: allowing the investigations to proceed for a period of time to permit completion; limiting the continuation of investigations to subjects who are already participating; requiring transfer of responsibility for further review of the investigations to an IRB that is in compliance with FDA standards; or terminating the investigation completely.²

The Center for Biologics and Research (CBER) shall provide each Center with jurisdiction over the product being studied in each ongoing clinical investigation with all information CBER possesses regarding any ongoing clinical investigations reviewed by TABS RRC.

Sincerely,

Luciana Borio, M.D.
Acting Chief Scientist

Enclosure

² See 43 Fed. Reg. 35186, 35195-196 (1978).