Principal Investigator Notification:

From: Mayo Clinic IRB
To: Shabana Pasha
CC: Allison Adams
Grant Erickson
Michael Lee
Shabana Pasha
Lisa Stewart

Re: **IRB Application #:** 13-008267
Title: Autoantibody Biomarker Discovery in Inflammatory Bowel Disease using Immunoproteomics

IRBe Protocol Version: 0.01
IRBe Version Date: 12/9/2013 11:04 AM

IRB Approval Date: 2/26/2014
IRB Expiration Date: 2/25/2015

The above referenced application is approved by expedited review procedures (45 CFR 46.110, item 5). This approval is valid for a period of 1 year. The Reviewer conducted a risk-benefit analysis, and determined the study constitutes minimal risk research. The Reviewer determined that this research satisfies the requirements of 45 CFR 46.111. The Reviewer notes submission of the application to the Biospecimens Subcommittee for review. The Reviewer reminds the investigator that biospecimens may not be used for this research until approval from the Biospecimen Subcommittee has been obtained. The Reviewer reviewed the Conflict of Interest (COI) Review Board determination related to Dr. Jonathan Leighton and Dr. Michael Picco. The Reviewer accepted the COI Review Board determination of no conflict of interest. An appropriate Data Use Agreement must be negotiated with Legal Contract Administration Unit because a limited data set is being sent outside Mayo Clinic.

The Reviewer approved waiver of the requirement to obtain informed consent in accordance with 45 CFR 46.116 as justified by the Investigator, and waiver of HIPAA authorization in accordance with applicable HIPAA regulations. The Reviewer reminds the Investigator to submit the fully executed IRB Authorization Agreement making Mayo the IRB of Record for Arizona State University via a modification.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO).
4) Compliance with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer