**Principal Investigator Notification:**

**From:** Mayo Clinic IRB
**To:** Heidi Connolly
**CC:** Christine Attenhofer
Heidi Connolly
Margaret Fuchs

**Re:** **IRB Application #:** 17-002507
**Title:** Cardiovascular abnormalities in Turner syndrome: frequency of anomalies of aorta and aortic valve and analysis of influencing factors

IRBe Protocol Version: 0.01
IRBe Version Date: 3/23/2017 12:28 PM

IRB Approval Date: 5/4/2017
IRB Expiration Date: 5/3/2020

The above referenced application is approved by expedited review procedures (45 CFR 46.110, item 5). This approval is valid for a period of 3 years. The Reviewer determined there is adequate justification for the inclusion of children's records as set forth in 45 CFR 46.404 and neonates as set forth in 45 CFR 46.205 (Subpart D). 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 approved waiver of the requirement to obtain informed consent and assent 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 approved the accrual of 200 subjects and to review data that exist through March 23, 2017.

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