

To: Mary Ellen Heisler

Cc:

Mary Ellen Heisler

Subject: eResearch System-Generated Notice of "Not Regulated" Status for HUM00160477

SUBMISSION INFORMATION

Title: Review of De-Identified Medical Affidavits of US Asylum Seekers who Experienced Family Separation

Full Study Title (if applicable): Review of De-Identified Medical Affidavits of US Asylum Seekers who Experienced Family Separation

Study eResearch ID: HUM00160477

Date of this System-Generated Notice: 3/5/2019

IRB "NOT REGULATED" STATUS:

Based on the information provided, the proposed study does not fit the definition of research involving human subjects (<u>45CFR46.102</u>) because the researchers intending to contribute to generalizable knowledge do not interact with human subjects, nor obtain identifiable private information or identifiable biospecimens.