Gmail

Mark Baker <mbaker@softlights.org>

OHRP Complaint #00698723 – No Action

Mark Baker <mbaker@softlights.org> Mon, May 20, 2024 at 1:42 PM
To: Mark Baker <mbaker@softlights.org>

From: **OASH SPS** <oashsps@hhs.gov>
Date: Mon, May 20, 2024 at 9:30 AM
Subject: OHRP Complaint #00698723 – No Action
To: mbaker@softlights.org <mbaker@softlights.org>

Thank you for contacting the Office for Human Research Protections (OHRP). Based on the information you provided, your complaint does not fall under OHRP's authority. Our office is responsible for the U.S. Department of Health and Human Services (HHS) regulations that protect people in research. Our regulations only apply to research with living individuals if the research is funded or conducted by HHS. Note that some research may be exempt from the regulations.

OHRP does not have authority over this matter and will not be able to pursue the matter on your behalf. No additional action will be taken.

For more information about OHRP's authority and other organizations that might be helpful, please see our website: https://www.hhs.gov/ohrp/compliance-and-reporting/submitting-a-complaint/index.html.

The description you provided of the complaint has been included below:

- This complaint is about the lack of supervision by the FDA CDRH over this real-world LED study. Rather than vetting LED Visible Light radiation in controlled experiments and then publishing performance standards to ensure photobiological, hormonal, neurological, and psychological safety, the FDA CDRH has allowed LED products to enter into the environment in an uncontrolled and unsupervised experiment, with the FDA CDRH not even collecting data on the impacts of LED products on the real-world participants.

Sincerely,
Division of Compliance Oversight
Office for Human Research Protections (OHRP)